

From: Ross, Sydney <Sydney.Ross@ncagr.gov>
Sent: Thursday, March 4, 2021 3:37 PM
To: Livingston, Pat <Livingston.Patricia@epa.gov>
Cc: Jones, Patrick <patrick.jones@ncagr.gov>
Subject: FW: [External] Complaint about Seresto

Hi Pat,

Here is all of the info I have from the complainant I spoke with yesterday. This is the information I sent to our toxicologists at DHHS. DHHS may reach out to her to answer some of her toxicology questions. If there is someone at EPA who would also be willing to speak with her or any of our other complainants about this issue, please let me know and I can direct them to that individual. Thank you for your help and hope you are well!

Yesterday an article was published on USA Today's Website https://apple.news/A78_uo4GjQWq_FP9GTVxg9w about the potential of Seresto Flea & Tick Collars causing harm to both animals and humans exposed to them. I have added the pesticide label for the Small or Large Seresto Dog Collar below. The active ingredients in these collars are imidacloprid (neonicotinoid) and flumethrin (pyrethroid) and they are produced by Bayer Animal Health.

Here is the description of the incident:

Today we received a call from NC resident [Ex. 6 Personal Privacy (PP)] with serious concerns about the collars. [Ex. 6 Personal Privacy (PP)] has been using the collars on her dogs for the last few years since she moved to NC from FL. She had a dog that passed away from 'unknown circumstances', skin issues and ultimately a tumor, that she used the collars on. She currently has been using a large dog Seresto Flea & Tick Collar on her 2 year old dog. She purchased the current collar from 1-800-petmeds. Her dog has vomited several times and often has, as she described it, a 'glazed look in it's eyes' and is unresponsive. She removed the collar from her dog's neck today after reading the article above. She also sleeps with her dog while the dog is wearing the collar and mentioned that she is often touching the dog's neck with her own while she is asleep. For this past two months she has been experiencing serious headaches when she wakes up and has had a few blood vessels pop in her brain. She went to see her doctor and a cardiologist and they have not been able to find the origin of her headaches. She has another doctor's appointment on March 11, 2021, but she has some questions she needs answered about the effects this chemical may have on her and her dog and whether or not exposure could be causing her health issues. She would also like to know what types of medical tests she should have done to see if she has been exposed. If possible, please contact [Ex. 6 Personal Privacy (PP)] to answer her questions, her phone number is [Ex. 6 Personal Privacy (PP)]. She requested that you leave a voice message if she does not answer.

<https://images-na.ssl-images-amazon.com/images/I/71IBSmlPrgL.pdf>

<https://fleascience.com/wp-content/uploads/2015/11/Product-Label-for-Bayer-Seresto-Collar-for-Dogs.pdf>

Sydney L. Ross

Pesticide Operations Specialist
North Carolina Department of Agriculture and Consumer Services
Structural Pest Control & Pesticides Division
1090 Mail Service Center
Raleigh, NC 27699-1090
(919) 857-4151
<http://www.ncagr.gov/SPCAP/index.htm>

From: Jones, Patrick <patrick.jones@ncagr.gov>
Sent: Thursday, March 4, 2021 3:26 PM
To: Livingston, Pat <Livingston.Patricia@epa.gov>; Ross, Sydney <Sydney.Ross@ncagr.gov>
Subject: Re: [External] Complaint about Seresto

Hey Pat. Sydney has that information. Thank you for your help!
Get [Outlook for iOS](#)

From: Livingston, Pat <Livingston.Patricia@epa.gov>
Sent: Thursday, March 4, 2021 3:08 PM
To: Jones, Patrick
Subject: [External] Complaint about Seresto

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Hi there! Well, the wheels at EPA are starting to turn on this Seresto issue. We were notified today that if we got any tips/complaints we should notify our External Affairs office (like media and press). I did contact someone in that office just a bit ago and told them that you had reported getting a complaint. Would you be willing to share the details of your complaint with me/us? If yes, please just send an email with the pertinent info. If not, just let me know that.

Thanks!

Pat

Message

From: Miller, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB7A864DD08445B0A59A63FA36836677-ROBERT MILLER]
Sent: 3/4/2021 7:40:47 PM
To: Biscoe, Melanie [Biscoe.Melanie@epa.gov]
Subject: Seresto/Flumethrin

Hi Melanie,

Is flumethrin your chemical? Here's a link to a news article that has place Seresto/Flumethrin and the EPA in the spotlight - <https://www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/>

Since Bayer sold Seresto to Elanco we have not received one incident report involving Seresto from Elanco. For years we received tens of thousands of incident reports involving Seresto from Bayer and now we are not receiving anything. It's difficult to imagine Elanco isn't receiving any incident reports for Seresto products.

Take care,

Bob

Message

From: Miller, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB7A864DD08445B0A59A63FA36836677-ROBERT MILLER]
Sent: 4/18/2016 1:14:48 PM
To: Nicholas Mastrota [Mastrota.Nicholas@epa.gov]
CC: Hopkins, Yvette [Hopkins.Yvette@epa.gov]; Panger, Melissa [Panger.Melissa@epa.gov]; Rivera-Lupianez, Ana [Rivera-Lupianez.Ana@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]
Subject: FW: NPIC Annual Report and Supplements - Year 2
Attachments: ARpt2015-Final.pdf; ARpt2015Supplement.pdf; GY2015Eco.pdf; GY2015Vet.pdf

Hi Nick,

We received NPIC's Annual Report. The active ingredient bromethalin was involved in the most pet incident reports of any active ingredient. It's impossible to determine if the bromethalin pet incidents occurred inside or outside.

Seresto was involved in quite a few incidents reported to NPIC through the vet portal. Pet incidents can also be reported directly to NPIC not using the vet portal. We do not have those pet incident reports. We can request those pet incident reports from NPIC. Norm never entered pet incidents received from NPIC due to lack of staffing. I'm leaning toward entering pet incidents into IDS because unlike Norm I allow NOWCCs to enter individual incident data into IDS.

Bob

From: Rivera-Lupianez, Ana
Sent: Thursday, April 14, 2016 4:40 PM
To: Chen, Jonathan <Chen.Jonathan@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Gayoso, Jose <Gayoso.Jose@epa.gov>; Isbell, Diane <Isbell.Diane@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>; Panger, Melissa <Panger.Melissa@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Tanner, Lee <Tanner.Lee@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>
Cc: Kasai, Jeanne <Kasai.Jeanne@epa.gov>
Subject: NPIC Annual Report and Supplements - Year 2

Hi,

Attached are NPIC's Annual Report and Supplements for the second year of the coop agreement (Feb 2015-Feb 2016). Please let me know if you have any comments/questions.

Thanks,
Ana

Ana Rivera-Lupiañez
Office of Pesticide Programs
Environmental Protection Agency
rivera-lupianez.ana@epa.gov
(703) 308-6841

From: Kaci Buhl [<mailto:buhlk@ace.orst.edu>]
Sent: Thursday, April 14, 2016 4:24 PM
To: Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>
Cc: Marcus, Craig <Craig.Marcus@oregonstate.edu>; Dave.Stone@oregonstate.edu
Subject: NPIC Annual Report and Supplements - Year 2

Hello Ana,

You'll find the following summary documents for Year 2 attached:

- The formal Annual Report
- A supplement showing a snapshot of cases with compelling certainty and severity
- A compilation of all 48 Vet reports received
- A compilation of all 14 Eco reports received

Thanks!

Kaci Buhl
Project Coordinator
National Pesticide Information Center
Oregon State University
Department of Environmental & Molecular Toxicology
541-737-8330
buhlk@ace.orst.edu

Delivery Report

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 3/8/2021 9:51:39 PM
To: Overbey, Dian [Overbey.Dian@epa.gov]
Subject: Read: VIN and Snopes press inquiries on Seresto

Importance: High

Your message

To: Rosenblatt, Daniel; Echeverria, Marietta
CC: Ozmen, Shamus; Britton, Cathryn; Akerman, Gregory; Vogel, Dana; Herrick, Jacquelyn; Wilbur, Donald; Miller, David; Reaves, Elissa
Subject: VIN and Snopes press inquiries on Seresto
Sent: 3/5/2021 6:11:02 PM

was read 3/8/2021
on 9:50:57
PM

Delivery Report

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 3/8/2021 9:51:39 PM
To: Overbey, Dian [Overbey.Dian@epa.gov]
Subject: Read: Draft response to VIN press inquiry on Seresto

Importance: High

Your message

To: Vogel, Dana; Akerman, Gregory; Wilbur, Donald; Reaves, Elissa; Britton, Cathryn; Rosenblatt, Daniel; Herrick, Jacquelyn; Miller, David
CC: Ozmen, Shamus; Echeverria, Marietta
Subject: Draft response to VIN press inquiry on Seresto
Sent: 3/5/2021 2:45:18 PM

was read 3/8/2021
on 9:51:16
PM

Delivery Report

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 3/16/2021 5:02:59 PM
To: Overbey, Dian [Overbey.Dian@epa.gov]
Subject: Read: Media request, JAVMA, seresto collars

Importance: High

Your message

To: Saunders, Jennifer; Herrick, Jacquelyn
CC: Echeverria, Marietta; Aubee, Catherine; Rosenblatt, Daniel
Subject: FW: Media request, JAVMA, seresto collars
Sent: 3/16/2021 4:20:24 PM

was read 3/16/2021
on 5:02:51
PM

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 4/14/2016 2:00:31 PM
To: Godfrey, Victoria (HC/SC) [victoria.godfrey@canada.ca]
Subject: Accepted: FW: Seresto update
Location: E564

Start: 4/19/2016 2:00:00 PM
End: 4/19/2016 2:30:00 PM
Show Time As: Busy

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 6/3/2016 12:27:20 PM
To: Biscoe, Melanie [Biscoe.Melanie@epa.gov]
Subject: FW: Seresto Discussion
Location: DCRoomPYS7771D/Potomac-Yard-One
Start: 6/3/2016 5:00:00 PM
End: 6/3/2016 6:00:00 PM
Show Time As: Tentative

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 6/3/2016 4:37:13 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Seresto Discussion
Location: DCRoomPYS7771D/Potomac-Yard-One
Start: 6/3/2016 5:30:00 PM
End: 6/3/2016 6:30:00 PM
Show Time As: Busy

Appointment

From: Recore, Shanna [Recore.Shanna@epa.gov]
Sent: 5/3/2016 2:17:26 PM
To: Recore, Shanna [Recore.Shanna@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
CC: Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]
Subject: update regarding spot-ons and seresto
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/5/2016 1:00:00 PM
End: 5/5/2016 2:00:00 PM
Show Time As: Busy

Required Attendees: Miller, David; Evans, Elizabeth; Davis, Kable; Echeverria, Marietta; Nguyen, James; Sarkar, Bayazid; Breeden, Julie; Rossmeisl, Colleen
Optional Attendees: Arrington, Linda; Biscoe, Melanie; Adler, Bonnie

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/5/2016 1:37:07 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]

Subject: Conference Call with PMRA; Seresto
Location: DCRoomPYS7671C/Potomac-Yard-One

Start: 8/10/2016 6:30:00 PM
End: 8/10/2016 7:30:00 PM
Show Time As: Busy

Required Attendees: Echeverria, Marietta; Breeden-Alemi, Julie; Miller, David; Rossmeisl, Colleen; Recore, Shanna; Adler, Bonnie; Biscoe, Melanie

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 8/5/2016 1:58:01 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Conference Call with PMRA; Seresto
Location: DCRoomPYS7671C/Potomac-Yard-One
Start: 8/10/2016 6:30:00 PM
End: 8/10/2016 7:30:00 PM
Recurrence: (none)

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/3/2016 2:18:42 PM
To: Recore, Shanna [Recore.Shanna@epa.gov]
Subject: Accepted: update regarding spot-ons and seresto
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/5/2016 1:00:00 PM
End: 5/5/2016 2:00:00 PM
Show Time As: Busy

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 8/11/2016 8:59:46 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Seresto Discussion
Location: DCRoomPYS7100/Potomac-Yard-One
Start: 8/16/2016 12:00:00 PM
End: 8/16/2016 1:00:00 PM
Recurrence: (none)

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 8/16/2016 8:32:52 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Seresto Review
Location: DCRoomPYS7621B/Potomac-Yard-One
Start: 8/18/2016 8:00:00 PM
End: 8/18/2016 8:30:00 PM
Show Time As: Busy

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/16/2016 8:32:20 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]

Subject: Seresto Review
Location: DCRoomPYS7621B/Potomac-Yard-One

Start: 8/18/2016 8:00:00 PM
End: 8/18/2016 8:30:00 PM
Show Time As: Busy

Required Attendees: Miller, David; Echeverria, Marietta; Breeden-Alemi, Julie; Rossmeisl, Colleen

Appointment

From: DCRoomPYS7621B/Potomac-Yard-One [DCRoomPYS7621B@epa.gov]
Sent: 9/8/2016 1:42:39 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]

Subject: Accepted: seresto
Location: DCRoomPYS7621B/Potomac-Yard-One

Start: 9/8/2016 8:00:00 PM
End: 9/8/2016 8:30:00 PM

Recurrence: (none)

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 9/8/2016 1:43:12 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]

Subject: Accepted: seresto
Location: DCRoomPYS7621B/Potomac-Yard-One

Start: 9/8/2016 8:00:00 PM
End: 9/8/2016 8:30:00 PM
Show Time As: Busy

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/3/2016 2:19:19 PM
To: Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]
Subject: FW: update regarding spot-ons and seresto
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/5/2016 1:00:00 PM
End: 5/5/2016 2:00:00 PM
Show Time As: Tentative

Appointment

From: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Sent: 9/8/2016 2:44:34 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]

Subject: Accepted: seresto
Location: DCRoomPYS7621B/Potomac-Yard-One

Start: 9/8/2016 8:00:00 PM
End: 9/8/2016 8:30:00 PM
Show Time As: Busy

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 9/9/2016 1:13:52 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Piansay, Maria [Piansay.Maria@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]

Subject: Bayer (Seresto) Pre-Meeting
Location: DCRoomPYS7621B/Potomac-Yard-One

Start: 9/12/2016 6:30:00 PM
End: 9/12/2016 7:00:00 PM
Show Time As: Busy

Required Attendees: Guilaran, Yu-Ting; Vogel, Dana; Dan Rosenblatt; Arrington, Linda; Biscoe, Melanie; Piansay, Maria; Echeverria, Marietta

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 9/9/2016 1:14:25 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Bayer (Seresto) Pre-Meeting
Location: DCRoomPYS7621B/Potomac-Yard-One
Start: 9/12/2016 6:30:00 PM
End: 9/12/2016 7:00:00 PM
Recurrence: (none)

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 9/12/2016 5:29:59 PM
To: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Piansay, Maria [Piansay.Maria@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]

Subject: Bayer (Seresto) Pre-Meeting
Location: DCRoomPYS7621B/Potomac-Yard-One

Start: 9/12/2016 6:30:00 PM
End: 9/12/2016 7:00:00 PM
Show Time As: Tentative

Required Attendees: Guilaran, Yu-Ting; Vogel, Dana; Dan Rosenblatt; Arrington, Linda; Biscoe, Melanie; Piansay, Maria; Echeverria, Marietta

Appointment

From: Housenger, Jack [Housenger.Jack@epa.gov]
Sent: 9/13/2016 9:08:20 PM
To: Housenger, Jack [Housenger.Jack@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Piansay, Maria [Piansay.Maria@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Knorr, Michele [Knorr.Michele@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]
CC: Perlis, Robert [Perlis.Robert@epa.gov]

Subject: Seresto Pet Collar Briefing
Location: 12100 PY

Start: 9/20/2016 3:00:00 PM
End: 9/20/2016 4:00:00 PM
Show Time As: Busy

Required Attendees: Goodis, Michael; Echeverria, Marietta; Davis, Kable; Rosenblatt, Daniel; Guilaran, Yu-Ting; Arrington, Linda; Biscoe, Melanie; Piansay, Maria; Vogel, Dana; Miller, David; Rossmeisl, Colleen; Knorr, Michele; Keigwin, Richard
Optional Attendees: Perlis, Robert

Appointment

From: Recore, Shanna [Recore.Shanna@epa.gov]
Sent: 5/3/2016 2:28:20 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
CC: Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]
Subject: update regarding spot-ons and seresto
Location: DCRoomPYS10771/Potomac-Yard-One

Start: 5/5/2016 1:00:00 PM
End: 5/5/2016 2:00:00 PM
Show Time As: Tentative

Required Attendees: Miller, David; Evans, Elizabeth; Davis, Kable; Echeverria, Marietta; Nguyen, James; Sarkar, Bayazid; Breeden, Julie; Rossmeisl, Colleen
Optional Attendees: Arrington, Linda; Biscoe, Melanie; Adler, Bonnie

Appointment

From: Godfrey, Victoria (HC/SC) [victoria.godfrey@canada.ca]
Sent: 4/14/2016 1:57:13 PM
To: Godfrey, Victoria (HC/SC) [victoria.godfrey@canada.ca]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Bruce, Dana (HC/SC) [dana.bruce@canada.ca]; Recore, Shanna [Recore.Shanna@epa.gov]
Subject: FW: Seresto update
Location: E564
Start: 4/19/2016 2:00:00 PM
End: 4/19/2016 2:30:00 PM
Show Time As: Busy

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 5/11/2016 3:01:30 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Knorr, Michele [Knorr.Michele@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]

Subject: Meeting with Bayer; Seresto
Location: DCRoomPYS7100/Potomac-Yard-One

Start: 6/9/2016 7:00:00 PM
End: 6/9/2016 8:00:00 PM
Show Time As: Busy

Required Attendees: Echeverria, Marietta; Miller, David; Knorr, Michele; Breeden, Julie; Biscoe, Melanie; Adler, Bonnie; Rossmeisl, Colleen; Recore, Shanna

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/11/2016 3:20:30 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Meeting with Bayer; Seresto
Location: DCRoomPYS7100/Potomac-Yard-One
Start: 6/2/2016 3:00:00 PM
End: 6/2/2016 4:00:00 PM
Show Time As: Busy

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/12/2016 12:53:04 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Meeting with Bayer; Seresto
Location: DCRoomPYS7100/Potomac-Yard-One
Start: 6/9/2016 7:00:00 PM
End: 6/9/2016 8:00:00 PM
Show Time As: Busy

Appointment

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 5/24/2016 8:04:58 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Britton, Wade [Britton.Wade@epa.gov]; VanAlstine, Julie [VanAlstine.Julie@epa.gov]; Hawkins, Monica [Hawkins.Monica@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
CC: Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]
Subject: Update -- and Discuss upcoming spot-on and Seresto activities and meetings
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/25/2016 12:30:00 PM
End: 5/25/2016 1:30:00 PM
Show Time As: Busy

Required Attendees: Recore, Shanna; Sarkar, Bayazid; Evans, Elizabeth; Rossmeisl, Colleen; Breeden-Alemi, Julie; Echeverria, Marietta; Nguyen, James; Davis, Kable; Britton, Wade; VanAlstine, Julie; Hawkins, Monica; Davis, Donna
Optional Attendees: Adler, Bonnie; Biscoe, Melanie; Arrington, Linda

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/23/2016 8:34:06 AM
To: Miller, David [Miller.DavidJ@epa.gov]
Subject: Accepted: Update -- and Discuss upcoming spot-on and Seresto activities and meetings
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/25/2016 12:30:00 PM
End: 5/25/2016 1:30:00 PM
Recurrence: (none)

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/24/2016 5:42:18 PM
To: Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]
Subject: FW: Update -- and Discuss upcoming spot-on and Seresto activities and meetings
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/25/2016 12:30:00 PM
End: 5/25/2016 1:30:00 PM
Show Time As: Tentative

Appointment

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 5/24/2016 8:36:18 PM
To: Recore, Shanna [Recore.Shanna@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Britton, Wade [Britton.Wade@epa.gov]; VanAlstine, Julie [VanAlstine.Julie@epa.gov]; Hawkins, Monica [Hawkins.Monica@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
CC: Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]
Subject: Update -- and Discuss upcoming spot-on and Seresto activities and meetings
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/25/2016 12:30:00 PM
End: 5/25/2016 1:30:00 PM
Show Time As: Tentative

Required Attendees: Recore, Shanna; Sarkar, Bayazid; Evans, Elizabeth; Rossmeisl, Colleen; Breeden-Alemi, Julie; Echeverria, Marietta; Nguyen, James; Davis, Kable; Britton, Wade; VanAlstine, Julie; Hawkins, Monica; Davis, Donna
Optional Attendees: Adler, Bonnie; Biscoe, Melanie; Arrington, Linda

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 5/25/2016 4:21:12 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Knorr, Michele [Knorr.Michele@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]

Subject: Internal Seresto Meeting
Location: DCRoomPYS7671C/Potomac-Yard-One

Start: 6/7/2016 7:00:00 PM
End: 6/7/2016 8:00:00 PM
Show Time As: Busy

Required Attendees: Echeverria, Marietta; Miller, David; Knorr, Michele; Breeden-Alemi, Julie; Biscoe, Melanie; Adler, Bonnie

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/25/2016 4:37:35 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Internal Seresto Meeting
Location: DCRoomPYS7671C/Potomac-Yard-One
Start: 6/7/2016 7:00:00 PM
End: 6/7/2016 8:00:00 PM
Show Time As: Busy

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/27/2016 4:51:55 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Call with PMRA; Seresto
Location: DCRoomPYS7771D/Potomac-Yard-One
Start: 6/2/2016 5:00:00 PM
End: 6/2/2016 6:00:00 PM
Show Time As: Busy

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 5/27/2016 4:51:14 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]

Subject: Call with PMRA; Seresto
Location: DCRoomPYS7771D/Potomac-Yard-One

Start: 6/2/2016 5:00:00 PM
End: 6/2/2016 6:00:00 PM
Show Time As: Busy

Required Attendees: Echeverria, Marietta; Breeden-Alemi, Julie

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 6/2/2016 1:32:19 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lewis, Susan [Lewis.Susan@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]
CC: Bloom, Jill [Bloom.Jill@epa.gov]
Subject: Seresto Discussion
Location: DCRoomPYS7771D/Potomac-Yard-One
Start: 6/3/2016 5:30:00 PM
End: 6/3/2016 6:30:00 PM
Show Time As: Busy

Required Attendees: Guilaran, Yu-Ting; Lewis, Susan; Echeverria, Marietta; Breeden-Alemi, Julie; Arrington, Linda; Miller, David; Costello, Kevin; Biscoe, Melanie
Optional Attendees: Bloom, Jill

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 6/2/2016 2:17:37 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Seresto Discussion
Location: DCRoomPYS7771D/Potomac-Yard-One
Start: 6/3/2016 5:00:00 PM
End: 6/3/2016 6:00:00 PM
Recurrence: (none)

Message

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 4/19/2016 6:59:32 PM
To: Lewis, Susan [lewis.susan@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Herndon, George [herndon.george@epa.gov]
Subject: seresto update

We had a conference call with PMRA today regarding their review of the seresto collar. The PMRA team is briefing their management committee next week and are recommending against registration of the collar. Their review concludes that 80% of the incidents are classified as at least "possibly" related to the use of the collar. Additionally (and the first time we became aware of this issue), their human health assessment (post application/dermal and aggregate) indicates risks of concern to adults for the big dog scenario and to children for the small dog scenario. The toxicologist indicated that PMRA is using a different dermal endpoint than EPA did (NOEL of 0.5 versus 10).

We have requested PMRA's plausibility assessment; causality assessment; and human health risk assessment. We will have a follow call with them after their briefing.

Please let me know if you need additional information.

Marietta

Marietta Echeverria, Chief
Invertebrate & Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
703-305-8578
<http://www.epa.gov/pesticide-registration>

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/3/2016 2:19:19 PM
To: Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]
Subject: FW: update regarding spot-ons and seresto
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/5/2016 1:00:00 PM
End: 5/5/2016 2:00:00 PM
Show Time As: Tentative

-----Original Appointment-----

From: Recore, Shanna
Sent: Tuesday, May 03, 2016 10:17 AM
To: Recore, Shanna; Miller, David; Evans, Elizabeth; Davis, Kable; Echeverria, Marietta; Nguyen, James; Sarkar, Bayazid; Breeden, Julie; Rossmeisl, Colleen
Subject: update regarding spot-ons and seresto
When: Thursday, May 05, 2016 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS10771/Potomac-Yard-One

Let's meet for an update on where we are and next steps for spot-ons and Seresto.

Message

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/4/2016 5:11:39 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]
Subject: RE: update regarding spot-ons and seresto

I haven't seen an agenda. I'm assuming it's pretty set and we are not on it.

From: Miller, David
Sent: Wednesday, May 04, 2016 1:06 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: FW: update regarding spot-ons and seresto

Marietta and Bo,

Thoughts below on whether you want me/us to attend (or attend and present) at PPDC? The PPDC is held on the same two days as a meeting at CLA that I need to attend. Not a problem – we just need to be sure that the CLA meeting doesn't directly conflict with the time you may like me to be at PPDC – so it would be useful to know the PPDC schedule.

David.

From: Miller, David
Sent: Tuesday, May 03, 2016 2:45 PM
To: Recore, Shanna <Recore.Shanna@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Cc: Arrington, Linda <Arrington.Linda@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Adler, Bonnie <Adler.Bonnie@epa.gov>
Subject: RE: update regarding spot-ons and seresto

Some other topics to consider for our Thursday:

- PPDC on May 18/19 (?) – do you want us to present anything on spot-ons/pet incidents to PPDC?
- FDA meetings
 - a couple weeks ago
 - 04 May in afternoon to finalize FDA comments/template
- Spot on annual reports
- Upcoming 13 May meeting morning with Safetycall's Rick Kingston (he will be in town anyway)
 - Spot-on's (including annual report status)
 - PSP
- Schedule to put out/release template (next week?)-what needs to happen? Pilot period? Asking for volunteers? Next steps? Etc
- Webinar on what we do with spot on data (end of May?)

- Seresto update
 - Most recent incident report (see below)
 - PMRA plans

Ideas on others?

-----Original Appointment-----

From: Recore, Shanna

Sent: Tuesday, May 03, 2016 10:17 AM

To: Recore, Shanna; Miller, David; Evans, Elizabeth; Davis, Kable; Echeverria, Marietta; Nguyen, James; Sarkar, Bayazid; Breeden, Julie; Rossmeisl, Colleen

Cc: Arrington, Linda; Biscoe, Melanie; Adler, Bonnie

Subject: update regarding spot-ons and seresto

When: Thursday, May 05, 2016 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomPYS10771/Potomac-Yard-One

Let's meet for an update on where we are and next steps for spot-ons and Seresto.

Here is a look at the seasonal trend for Seresto with the new FY16 Q1 incidents

<< OLE Object: Picture (Device Independent Bitmap) >>

<< OLE Object: Picture (Device Independent Bitmap) >>

Message

From: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Sent: 5/11/2016 2:30:03 PM
To: Davis, Kable [Davis.Kable@epa.gov]
CC: Miller, David [Miller.DavidJ@epa.gov]
Subject: Re: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

We need to talk to ogc. It looks like they are inviting council.

Sent from my iPhone

On May 11, 2016, at 8:21 AM, Davis, Kable <Davis.Kable@epa.gov> wrote:

Hi David and Marietta –

Bayer is asking for a meeting regarding Seresto. They would like a status of our review and an understanding of the intent. I don't mind scheduling the meeting, however will be in position to provide that information by early June?

Thanks much,
Bo

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Wednesday, May 11, 2016 8:13 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Dear Mr. Davis,
Bayer HealthCare, Animal Health Division, is requesting a meeting with the Agency regarding the subject product.

The purpose of the meeting is for:

1. The Agency to provide us with an update regarding its current review of the incident data and other information we provided
2. Bayer to provide a brief overview of our interpretation of the information
3. The Agency to provide Bayer with an understanding of the Agency's intentions and next steps

We therefore, request that you schedule a 1-1/2 hour meeting with the appropriate members of the Agency for an effective discussion.

We suggest a convenient time on either June 2 or June 8th.

Attending from Bayer HealthCare will be:

- <!--[if !supportLists]--><!--[endif]-->Robert Zolynas, Head of Global Development
- <!--[if !supportLists]--><!--[endif]-->Bruce Martin, Director of Regulatory Affairs
- <!--[if !supportLists]--><!--[endif]-->Douglas Spilker, Manager of EPA Regulatory Affairs
- <!--[if !supportLists]--><!--[endif]-->Will Heeb, Manager of Pharmacovigilance
- <!--[if !supportLists]--><!--[endif]-->Jessica Monachello, Bayer General Legal Council
- <!--[if !supportLists]--><!--[endif]-->Roger Martella, Sidley Austin LLP

Please let us know as soon as possible so we can make appropriate travel plans.

Best Regards,

Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs

Bayer Animal Health
Bayer HealthCare LLC
P.O. Box 390
Shawnee Mission, KS 66201-0390
USA

Office: +1 -913-268-2751
Mobile: +1 -816-506-3102
Email: doug.spilker@bayer.com

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/24/2016 5:42:18 PM
To: Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]
Subject: FW: Update -- and Discuss upcoming spot-on and Seresto activities and meetings
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/25/2016 12:30:00 PM
End: 5/25/2016 1:30:00 PM
Show Time As: Tentative

-----Original Appointment-----

From: Miller, David
Sent: Sunday, May 22, 2016 5:39 PM
To: Miller, David; Recore, Shanna; Sarkar, Bayazid; Evans, Elizabeth; Rossmeisl, Colleen; Breeden-Alemi, Julie; Echeverria, Marietta; Nguyen, James; Davis, Kable
Subject: Update -- and Discuss upcoming spot-on and Seresto activities and meetings
When: Wednesday, May 25, 2016 8:30 AM-9:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS10771/Potomac-Yard-One

To include discussion of the following meetings:

- AHI meeting
- Bayer Seresto Meeting
- Spot-on Webinar

And a recap of the meeting last week with Rick Kingston.

And PMRA status re: Seresto (any new info), including causality analysis

Message

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 5/31/2016 6:26:46 PM
To: dana.bruce@canada.ca; victoria.godfrey@canada.ca
CC: Davis, Kable [Davis.Kable@epa.gov]
Subject: FW: Seresto

Hi Dana and Vicky,

Thank you for agreeing to have this call with us re: seresto. We have a meeting with Bayer on their US registration on June 9th and would like to know about the status in PMRA before that meeting. Since Bo and I are in the Registration Division here at OPP, I was wondering if you have been working with someone equivalent in the Registration Directorate at PMRA that we should include on the call. Thanks again.

Regards,
Marietta

Marietta Echeverria, Chief
Invertebrate & Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
703-305-8578
<http://www.epa.gov/pesticide-registration>

From: Davis, Kable
Sent: Tuesday, May 31, 2016 10:57 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: FW: Seresto

Hi Marietta – here is the email chain with PMRA.

From: Davis, Kable
Sent: Friday, May 27, 2016 12:50 PM
To: 'Bruce, Dana (HC/SC)' <dana.bruce@canada.ca>
Cc: Godfrey, Victoria (HC/SC) <victoria.godfrey@canada.ca>
Subject: RE: Seresto

Perfect. Let's plan on making the call next Thursday (6/2/16) at 1:00 pm EST. Below is the call-in information.

Call-in No: Ex. 6 PP - conference code/call in number
Conf. Code

Have a wonderful weekend.
Bo

Kable Bo Davis
Product Manager 3

Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Bruce, Dana (HC/SC) [<mailto:dana.bruce@canada.ca>]
Sent: Friday, May 27, 2016 12:47 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Godfrey, Victoria (HC/SC) <victoria.godfrey@canada.ca>
Subject: RE: Seresto

We are available both of those times.

Dana.

From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: 2016-05-27 12:40 PM
To: Bruce, Dana (HC/SC)
Subject: RE: Seresto

Great news. Are you available next Tuesday (5/31) at 10:00 am EST or next Thursday (6/2) at 1:00 pm EST? If so, I'll send out the call-in information.

Thanks again.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Bruce, Dana (HC/SC) [<mailto:dana.bruce@canada.ca>]
Sent: Friday, May 27, 2016 12:34 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Subject: RE: Seresto

No worries! I'd be happy to meet with you re: Seresto.

Dana

Dana Bruce

Manager, Incident Reporting Program
Pest Management Regulatory Agency,
Health Canada / Government of Canada
Tel: 613-736-3479

Gestionnaire du Programme de déclaration d'incident
Agence de la réglementation de la lutte antiparasitaire
Santé Canada / Gouvernement du Canada
Tél: 613-736-3479

From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: 2016-05-27 10:26 AM
To: Godfrey, Victoria (HC/SC); Bruce, Dana (HC/SC)
Subject: RE: Seresto

My apologies, Dana. I didn't mean to call you by your last name.

From: Davis, Kable
Sent: Friday, May 27, 2016 10:25 AM
To: 'Godfrey, Victoria (HC/SC)' <victoria.godfrey@canada.ca>; Bruce, Dana (HC/SC) <dana.bruce@canada.ca>
Subject: RE: Seresto

Thanks so much, Vicky.

Bruce – would you mind if I scheduled a time next week so Marietta and I could have a short discussion regarding Seresto?

Enjoy the day,
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Godfrey, Victoria (HC/SC) [<mailto:victoria.godfrey@canada.ca>]
Sent: Friday, May 27, 2016 10:23 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Bruce, Dana (HC/SC) <dana.bruce@canada.ca>
Subject: RE: Seresto

Hi Bo,

Dana Bruce (Dana.Bruce@canada.ca) would be Marietta's counterpart. I've cc'd her on this email as well.

Thanks – have a great weekend as well!

Vicky

Victoria Godfrey

Incident Reporting Analyst, Incident Reporting Program
Pest Management Regulatory Agency/Government of Canada
victoria.godfrey@canada.ca/613-736-3769

Analyste, déclaration des incidents, Programme de déclaration d'incident
Agence de réglementation de la lutte antiparasitaire/Gouvernement du Canada
victoria.godfrey@canada.ca/613-736-3769

From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: 2016-05-27 7:52 AM

To: Godfrey, Victoria (HC/SC)

Subject: Seresto

Hi Vicky –

I hope all is well. Shanna Recore gave me your contact information. My name is Bo Davis and I'm a product manager within the Registration Division at EPA. My team is responsible for maintaining the Seresto registration and my branch chief, Marietta Echeverria, was hoping to have an informal discussion with her counterpart at PMRA. Would you happen to know who exactly that would be? If so, would you mind forwarding that information so I can reach out and hopefully schedule a call for next week? I appreciate the help.

Have a nice Friday and a great weekend.

Bo

Kable Bo Davis

Product Manager 3

Invertebrate & Vertebrate Branch 1

(703) 306-0415

davis.kable@epa.gov

Appointment

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 6/3/2016 12:27:20 PM
To: Biscoe, Melanie [Biscoe.Melanie@epa.gov]
Subject: FW: Seresto Discussion
Location: DCRoomPYS7771D/Potomac-Yard-One
Start: 6/3/2016 5:00:00 PM
End: 6/3/2016 6:00:00 PM
Show Time As: Tentative

-----Original Appointment-----

From: Davis, Kable
Sent: Thursday, June 02, 2016 9:32 AM
To: Davis, Kable; Guilaran, Yu-Ting; Lewis, Susan; Echeverria, Marietta; Breeden-Alemi, Julie; Arrington, Linda; Miller, David; Costello, Kevin
Subject: Seresto Discussion
When: Friday, June 03, 2016 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS7771D/Potomac-Yard-One

Let' meet and discuss the appropriate next steps for how to review the incidents for Seresto. Should the review be folded into reg review or should something be done more quickly?

Call-in No: Ex. 6 PP - conference code/call in number
Conf. Code:

Message

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 6/3/2016 12:26:03 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lewis, Susan [Lewis.Susan@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]
Subject: RE: Seresto Discussion

I'll catch you up next week.

From: Miller, David
Sent: Thursday, June 02, 2016 11:41 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Lewis, Susan <Lewis.Susan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Arrington, Linda <Arrington.Linda@epa.gov>; Costello, Kevin <Costello.Kevin@epa.gov>
Subject: Re: Seresto Discussion

I am at offsite Codex delegate training all day today and tomorrow, but I don't necessarily have to be at your Friday meeting, and can catch up next week.

From: Davis, Kable
Sent: Thursday, June 2, 2016 10:02 AM
To: Guilaran, Yu-Ting; Lewis, Susan; Echeverria, Marietta; Breeden-Alemi, Julie; Arrington, Linda; Miller, David; Costello, Kevin
Subject: Seresto Discussion
When: Friday, June 3, 2016 1:00 PM-2:00 PM.
Where: DCRoomPYS7771D/Potomac-Yard-One

Let' meet and discuss the appropriate next steps for how to review the incidents for Seresto. Should the review be folded into reg review or should something be done more quickly?

Call-in No: Ex. 6 PP - conference code/call in number
Conf. Code

Message

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 2/11/2016 12:48:50 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]
CC: Breeden, Julie [Breeden.Julie@epa.gov]
Subject: RE: Question on Veterinary PV-Works/PV-Analyzer compatibilities with respect to export to MS Excel template

David, Thanks for the update. A couple of questions/points:

- 1) For the call with PV-Works (Ennov), could you invite Julie Breeden (if it hasn't already occurred)?
- 2) Before we got out to the registrants with anything

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) Is this doable in the February timeframe? Please let us know if we should have a meeting to further describe what RD is looking for in this review.

Thank you and your team for the diligent work on this project!

Marietta

From: Miller, David
Sent: Tuesday, February 09, 2016 11:49 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: FW: Question on Veterinary PV-Works/PV-Analyzer compatibilities with respect to export to MS Excel template

A quick update on the status of our external communications with respect to Seresto:

1. You should have received an email I sent yesterday from the European Medicines Agency on Seresto. They said: talk to the Germans. So, I sent an email to them yesterday asking the same question.
2. See below for the response from a company that makes commercial pharmacovigilance software. I understand Bayer Animal Health – and maybe Safety Call, Inc. – use this. While we will stick with our spreadsheet format for getting in the spot on data (we can't require them to buy and use commercial software), we thought it was important that Spot-on registrants who do use some commercially available software be able to export their data to an Excel format along the lines of our template. So.... we will be asking the PV-Works people this in a future call with them. Recall Bayer said that they had problems getting their Seresto data (from what I believe was in PV-Works) into our spreadsheet.
3. James is finishing up the spreadsheet template for the spot-on products for external (e.g, FDA) review.
4. We understand that you would likely like to get a note out to registrants during March to let them know that – for most of them – quarterly reporting is no longer required. March is good so as to avoid them starting reporting on this for the January through March 2016 quarter. However, we may want them to try out the template for January through March so as we can offer feedback. And then have them continue with it for the March through December time frame.

Do you two want to be involved in the call with the PV-Works folks (now apparently part of Ennov) ?

David

From: Nic Pillinger [<mailto:nic.pillinger@ennov.com>]

Sent: Tuesday, February 09, 2016 11:30 AM

To: Miller, David <Miller.DavidJ@epa.gov>

Subject: FW: Question on Veterinary PV-Works/PV-Analyzer compatibilities with respect to export to MS Excel template

Hi David

I'd be very happy to talk to you about all of your requirements for handling PV data. As you know we are already working with FDA CVM and USDA CVB in this area. When is a good time for a call and / or demo of the solutions?

Regards

Nic

P.S. As you'll see from my sign-off below, Assured Information System the original developers of the PV-Works and PV-Analyser software, are now part of Ennov – a supplier of various other software solutions to the life sciences sector. That said, the PV operation continues with the legal company name of Assured, although we often market ourselves as Ennov PV. I have personally been working with the PV division for 13 years and have a lot of direct experience in working with these previous Regulatory projects.

Nic Pillinger

Director of Pharmacovigilance Products



Email nic.pillinger@ennov.com

Office +44 (0)1480 212223

Visit us <http://www.ennov.com>

From: Miller, David [<mailto:Miller.DavidJ@epa.gov>]

Sent: 08 February 2016 23:13

To: info@assuredpv.com

Subject: Question on Veterinary PV-Works/PV-Analyzer compatibilities with respect to export to MS Excel template

We are currently considering ways/formats that we might like some veterinary pharmacovigilance data to be submitted to us, and would ideally like it to be in a way that would generally be compatible with available commercial software like PV-Works. Please call me about the ability of the PV-Works and/or PV-Analyzer software to export into a pre-formatted MS Excel worksheet template that we are developing.

Please call me at the number below at your convenience.

Tx.

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicovigilance & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

Message

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 9/14/2016 1:04:23 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Re: Seresto Briefing Document

Looks good. Send it for team review (hed, Colleen, ogc, prd). I'll review it once again before we send it to DDs. Thanks!

Sent from my iPhone

On Sep 14, 2016, at 8:01 AM, Davis, Kable <Davis.Kable@epa.gov> wrote:

Hi Marietta –

Here is the draft briefing document for next week's meeting with Jack. Let me know if you want anything revised. Also, I was questioning how I formatted the "Options for Next Steps" section. Let me know if you were envisioning something different.

Hope your trip is going well.
Bo

<Seresto Briefing Document.docx>

Message

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 4/21/2016 5:55:01 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: Automatic reply: PMRA Seresto update from conference call today

I will be out of the office on government travel attending the CCPR48/Codex meeting beginning Thursday April 21 and returning to the office on Monday 02 May. I should have access to email during this time, and will be checking it on at least a daily basis.

If you need assistance during this time, please contact Matthew Crowley who will be acting branch chief for CEB/TEB at crowley.matthew@epa.gov.

Message

From: Recore, Shanna [Recore.Shanna@epa.gov]
Sent: 4/22/2016 12:08:11 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: PMRA Seresto update from conference call today

Deborah Ramsingh didn't say when, just that "We might be able to send you a version of our human health risk assessment once it is a little more finalized."

From: Echeverria, Marietta
Sent: Thursday, April 21, 2016 1:55 PM
To: Recore, Shanna <Recore.Shanna@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>
Cc: Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>; Adler, Bonnie <Adler.Bonnie@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Arrington, Linda <Arrington.Linda@epa.gov>
Subject: RE: PMRA Seresto update from conference call today

David et al.,
I spoke with Donna Davis this morning. She is having her team write up a brief technical summary (1-2 paragraphs) describing the endpoints. She feels pretty comfortable that our team is confident with our tox endpoint because they have looked at it for reg review. There is an outstanding question about **Ex. 5 DP - Ex.4 Potential Claim**

Ex. 5 DP - Ex.4 Potential Claim PRD is hosting a call with Bayer tomorrow on this issue.

Shanna, Did PMRA say when they could share the assessment?

Thanks,
Marietta

From: Recore, Shanna
Sent: Wednesday, April 20, 2016 8:53 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>
Cc: Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>
Subject: RE: PMRA Seresto update from conference call today

Vicky (from PMRA) also said that they will be in touch next week, after the second director meeting, to schedule a conference call regarding PMRA's decision. She said the meeting will be on Thursday but she is not sure if it will be morning or afternoon.

From: Miller, David
Sent: Wednesday, April 20, 2016 4:31 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>
Cc: Recore, Shanna <Recore.Shanna@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>
Subject: FW: PMRA Seresto update from conference call today

Just FYI – see below

Also, I will be on travel beginning tomorrow through 01 May, back in office on 02 May. Matt C. is acting. I've asked folks here to see you later this week or early next about what you in RD to be done on the human exposure side to see why there is a difference with Canada. Shanna has communicated with Canada, got the MRIDs, and located the tox DER's. Anyway, they will talk to you, as it should probably be RD that speaks to the pertinent branch here in HED about what you'd like to be done or not done. My thinking as per our last conversation between you/me/Shanna:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

David.

From: Recore, Shanna

Sent: Wednesday, April 20, 2016 2:55 PM

To: Miller, David <Miller.DavidJ@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>

Subject: FW: PMRA Seresto update from conference call today

I had a voicemail from Vicky Godfrey from PMRA when I got back to my desk. She said that they had the directors meeting today and that the directors agreed that the collar should not be registered.

From: Recore, Shanna

Sent: Tuesday, April 19, 2016 12:55 PM

To: Miller, David <Miller.DavidJ@epa.gov>

Cc: Evans, Elizabeth <evans.elizabeth@epa.gov>

Subject: PMRA Seresto update from conference call today

PMRA met with their health directorate last week and recommended against supporting registration of the Seresto collar. They looked at the human major and moderate incidents and the domestic animal death and major incidents and determined that 80% of the incidents were possibly related to the use of the collar. The health directorate agreed that they should not support registration and they will be briefing their management tomorrow.

PMRA's human exposure assessment also does not support registration of either the large or small dog collar. They did use EPA's SOPs. But they used a different NOAEL than we did for short-term dermal. We used a NOAEL of 10 and they used 0.5. I have requested the draft human exposure review. They also used a wipe study that they requested and EPA does not have. Bo is requesting the wipe study from Bayer.

The sharing of the PMRA Seresto incident causality analysis with EPA was scheduled to occur in March, however, this sharing was delayed again because PMRA found errors that needed to be corrected, this edited causality analysis is now under management review and that should be wrapping up shortly.

Follow-up action items:

Vicky from PRMA is going to call me tomorrow after the management meeting to give an update.

PMRA is going to, over the next couple weeks, send us the causality analysis, the updated plausibility analysis, and arrange another conference call after a 2nd management meeting that they anticipate taking place next week.

Shanna Recore
Health Effects Division
Office of Pesticide Programs

U.S. Environmental Protection Agency
(703) 308-9399

Message

From: Arrington, Linda [Arrington.Linda@epa.gov]
Sent: 5/3/2016 2:19:21 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: Automatic reply: update regarding spot-ons and seresto

I will be out of the office on Tues May 3rd. Please contact Jill Bloom for assistance.
Have a great day!

Linda

Message

From: Arrington, Linda [Arrington.Linda@epa.gov]
Sent: 5/2/2016 12:31:53 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]
Subject: RE: seresto

thanks

Linda Arrington, Branch Chief
RMIB 5
Pesticide Re-evaluation Division
Office 703 305 6249
Fax 703 308 8005

From: Echeverria, Marietta
Sent: Monday, May 02, 2016 7:45 AM
To: Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Arrington, Linda <Arrington.Linda@epa.gov>
Subject: Fwd: seresto

FYI

Sent from my iPhone

Begin forwarded message:

From: "Recore, Shanna" <Recore.Shanna@epa.gov>
Date: May 2, 2016 at 7:30:34 AM EDT
To: "Miller, David" <Miller.DavidJ@epa.gov>, "Echeverria, Marietta" <Echeverria.Marietta@epa.gov>, "Davis, Kable" <Davis.Kable@epa.gov>, "Breedon, Julie" <Breedon.Julie@epa.gov>, "Rossmeisl, Colleen" <Rossmeisl.Colleen@epa.gov>, "Evans, Elizabeth" <Evans.Elizabeth@epa.gov>, "Sarkar, Bayazid" <Sarkar.Bayazid@epa.gov>, "Nguyen, James" <Nguyen.James@epa.gov>, "Biscoe, Melanie" <Biscoe.Melanie@epa.gov>
Subject: FW: seresto

Vicky Godfrey (from PMRA) informed me on Friday that PMRA has not decided on next steps yet regarding seresto, but will be in touch when they find out more. I'll keep everyone posted.

From: Godfrey, Victoria (HC/SC) [mailto:victoria.godfrey@canada.ca]
Sent: Friday, April 29, 2016 2:58 PM
To: Recore, Shanna <Recore.Shanna@epa.gov>
Subject: RE: seresto

Hi Shanna,

Many of the DGs were not at the meeting yesterday, so Directors (who had been at the meeting last week!) sat in for them. As a result they did not decide on any next steps yet.

So we are basically where we were last week! They have not set a next meeting for us yet either.

Will be in touch when we find out more.

Have a good weekend!

Vicky

Victoria Godfrey

Incident Reporting Analyst, Incident Reporting Program
Pest Management Regulatory Agency/Government of Canada
victoria.godfrey@canada.ca/613-736-3769

Analyste, déclaration des incidents, Programme de déclaration d'incident
Agence de réglementation de la lutte antiparasitaire/Gouvernement du Canada
victoria.godfrey@canada.ca/613-736-3769

From: Recore, Shanna [<mailto:Recore.Shanna@epa.gov>]

Sent: 2016-04-29 1:59 PM

To: Godfrey, Victoria (HC/SC)

Subject: RE: seresto

Hi Vicky,

I just wanted to check in about the director generals meeting yesterday. Will you be able to have conference call with us next week to tell us about your next steps?

Thanks.

From: Godfrey, Victoria (HC/SC) [<mailto:victoria.godfrey@canada.ca>]

Sent: Wednesday, April 20, 2016 3:33 PM

To: Recore, Shanna <Recore.Shanna@epa.gov>

Subject: RE: seresto

Hi Shanna,

Yes, the meeting is next Thursday (I'm not sure if it's morning or afternoon yet).

I assume we will be in touch after that as well!

Vicky

Victoria Godfrey

Incident Reporting Analyst, Incident Reporting Program
Pest Management Regulatory Agency/Government of Canada
victoria.godfrey@canada.ca/613-736-3769

Analyste, déclaration des incidents, Programme de déclaration d'incident
Agence de réglementation de la lutte antiparasitaire/Gouvernement du Canada
victoria.godfrey@canada.ca/613-736-3769

From: Recore, Shanna [<mailto:Recore.Shanna@epa.gov>]

Sent: 2016-04-20 3:06 PM

To: Godfrey, Victoria (HC/SC)

Subject: seresto

Hi Vicky,

I'm sorry that I missed your call. Thanks for letting me know. Will the director generals meeting be next week?

Thanks,

Shanna Recore

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 5/11/2016 3:05:08 PM
To: Doug Spilker [doug.spilker@bayer.com]
CC: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Hi Doug —

Thanks for the email. I was able to schedule the meeting for June 2nd from 11:00 to 12:00 pm. Unfortunately, I was only able to schedule a 1-hour meeting. Let me know if this date and time work for you. Also, please forward any presentation materials prior to the meeting.

Thanks much,
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Wednesday, May 11, 2016 8:13 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Dear Mr. Davis,
Bayer HealthCare, Animal Health Division, is requesting a meeting with the Agency regarding the subject product.

The purpose of the meeting is for:

1. The Agency to provide us with an update regarding its current review of the incident data and other information we provided
2. Bayer to provide a brief overview of our interpretation of the information
3. The Agency to provide Bayer with an understanding of the Agency's intentions and next steps

We therefore, request that you schedule a 1-1/2 hour meeting with the appropriate members of the Agency for an effective discussion.

We suggest a convenient time on either June 2 or June 8th.

Attending from Bayer HealthCare will be:

- Robert Zolynas, Head of Global Development
- Bruce Martin, Director of Regulatory Affairs
- Douglas Spilker, Manager of EPA Regulatory Affairs
- Will Heeb, Manager of Pharmacovigilance
- Jessica Monachello, Bayer General Legal Council
- Roger Martella, Sidley Austin LLP

Please let us know as soon as possible so we can make appropriate travel plans.

Best Regards,

Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs

Bayer Animal Health
Bayer HealthCare LLC
P.O. Box 390
Shawnee Mission, KS 66201-0390
USA

Office: +1 -913-268-2751
Mobile: +1 -816-506-3102
Email: doug.spilker@bayer.com

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

Message

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 5/11/2016 3:17:29 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
CC: Recore, Shanna [Recore.Shanna@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
Subject: RE: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Ok. I checked with Shanna. Apparently, the default option for an all day event is to show as free. I will it to show as busy.

Sorry for the confusion.

From: Miller, David
Sent: Wednesday, May 11, 2016 11:11 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Recore, Shanna <Recore.Shanna@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Subject: RE: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

I have listed June 1 and June 2 as "all day" meetings for Codex. It is at a thin line at the top of my Calender. I will check to make sure I did it right, since it presumably should have blocked that day for me when you checked.

David.

From: Davis, Kable
Sent: Wednesday, May 11, 2016 11:09 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Recore, Shanna <Recore.Shanna@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Subject: RE: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

David – your calendar indicated you were free on June 2nd, which is why I scheduled it for that day. I'll see if something is free on the 8th. If not, should I keep it on 6/2?

From: Miller, David
Sent: Wednesday, May 11, 2016 11:06 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Recore, Shanna <Recore.Shanna@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Subject: RE: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Interesting that Seresto folks are inviting counsel. We will definitely was to involve/invite OGC, presumably.

Also- TEB folks spoke this a.m. on this and we are comfortable talking to Bayer on what we've done so far. I see they are requesting June 2 or June 8. A bit earlier than we'd like, but I don't expect us to have to do too much more so that is

ok. It would have been better later in the month and we could perhaps have a better idea of where Canada is and see the extent to which we may or may not be on the same page with them.

With respect to dates, I have a 2-day training for Codex on June 1 and June 2, so June 8 would be better. That is the same date as the AHL meeting which is in the (late) afternoon. So maybe a late morning meeting on June 8 with Bayer on Seresto would work out best.

One thing to keep in mind: we are comfortable with what we've done so far, and are very busy working on other non-Seresto stuff. We think that sharing what we've done so far with Bayer is a good thing to do, because we will be able to learn from them their thoughts and ratioale. We will – however –not be able to extend our analysis in any meaningful way, unless

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

David.

From: Davis, Kable
Sent: Wednesday, May 11, 2016 10:32 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Good catch. I didn't notice that. I'll go ahead and schedule the meeting.

From: Echeverria, Marietta
Sent: Wednesday, May 11, 2016 10:30 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Miller, David <Miller.DavidJ@epa.gov>
Subject: Re: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

We need to talk to ogc. It looks like they are inviting council.

Sent from my iPhone

On May 11, 2016, at 8:21 AM, Davis, Kable <Davis.Kable@epa.gov> wrote:

Hi David and Marietta –

Bayer is asking for a meeting regarding Seresto. They would like a status of our review and an understanding of the intent. I don't mind scheduling the meeting, however will be in position to provide that information by early June?

Thanks much,
Bo

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Wednesday, May 11, 2016 8:13 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Dear Mr. Davis,

Bayer HealthCare, Animal Health Division, is requesting a meeting with the Agency regarding the subject product.

The purpose of the meeting is for:

1. The Agency to provide us with an update regarding its current review of the incident data and other information we provided
2. Bayer to provide a brief overview of our interpretation of the information
3. The Agency to provide Bayer with an understanding of the Agency's intentions and next steps

We therefore, request that you schedule a 1-1/2 hour meeting with the appropriate members of the Agency for an effective discussion.

We suggest a convenient time on either June 2 or June 8th.

Attending from Bayer HealthCare will be:

- Robert Zolynas, Head of Global Development
- Bruce Martin, Director of Regulatory Affairs
- Douglas Spilker, Manager of EPA Regulatory Affairs
- Will Heeb, Manager of Pharmacovigilance
- Jessica Monachello, Bayer General Legal Council
- Roger Martella, Sidley Austin LLP

Please let us know as soon as possible so we can make appropriate travel plans.

Best Regards,

Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs

Bayer Animal Health
Bayer HealthCare LLC
P.O. Box 390
Shawnee Mission, KS 66201-0390
USA

Office: +1 -913-268-2751
Mobile: +1 -816-506-3102
Email: doug.spilker@bayer.com

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

Message

From: Crowley, Matthew [Crowley.Matthew@epa.gov]
Sent: 4/27/2016 12:18:41 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Baker, John D [John.Baker@fda.hhs.gov]; Garcia-Malene, Gorka [Gorka.Garcia-Malene@fda.hhs.gov]
CC: Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi John,

We have some folks out this week, so I think it would be best to push a conference call to later next week. Can you please send us your and others' availabilities for Wednesday (5/4) and Thursday (5/5)?

Also, if you have extensive/substantial comments can you provide them in an email so we can review them before the call? Might make for a smoother conversation.

Thanks,

Matt Crowley
US EPA / Office of Pesticide Programs
703-305-7606

From: Miller, David
Sent: Monday, April 25, 2016 11:44 AM
To: Baker, John D <John.Baker@fda.hhs.gov>; Garcia-Malene, Gorka <Gorka.Garcia-Malene@fda.hhs.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: Re: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Dear John,

First off, I want to offer you my sincere thanks to you all for meeting with us. We all felt it was a very productive meeting and a looking forward to this being the first of a number of future engagements. Secondly, I'd like to offer my apologies for not sending this Thank You earlier. I am in China now attending a week-long Codex meeting, having left last Thursday - so I had been racing around most of last week (and frankly the week before) getting prepared and neglected to send you a note of appreciation earlier.

Secondly, thank you very much for meeting among yourselves and going through the template spreadsheet. I will not be available for discussion until next week when I return, but will leave to my acting BC - Matt Crowley - to discuss it with the entire team and see if they'd like to go through this with you by phone this week - or wait until I return. I suspect they will want to meet with you by phone this week, but Matt Crowley will follow up with them.

Again, thanks very much for meeting with us and going through the template.

david

From: Baker, John D <John.Baker@fda.hhs.gov>

Sent: Monday, April 25, 2016 11:10 AM

To: Miller, David; Garcia-Malene, Gorka

Cc: Baker, John D

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi David,

We have been working on the spreadsheet and have some comments for you. Would you like to meet and discuss?

Thanks,

John

From: Miller, David [<mailto:Miller.DavidJ@epa.gov>]

Sent: Sunday, April 17, 2016 2:23 PM

To: Baker, John D; Garcia-Malene, Gorka

Cc: Recore, Shanna; Sarkar, Bayazid; Nguyen, James; Evans, Elizabeth; Rossmeisl, Colleen; Breeden, Julie

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hello John,

Please see attached agenda and EPA's presentation/discussion points.

We look forward to seeing you on Monday.

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)
Visit www.epa.gov/pesticides

From: Baker, John D [<mailto:John.Baker@fda.hhs.gov>]

Sent: Friday, April 15, 2016 10:02 AM

To: Miller, David <Miller.DavidJ@epa.gov>; Garcia-Malene, Gorka <Gorka.Garcia-Malene@fda.hhs.gov>

Cc: Baker, John D <John.Baker@fda.hhs.gov>

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Thanks David!

We look forward to your input and receiving the presentations.

I will be out of the office this afternoon.

Have a nice weekend,
John

From: Miller, David [<mailto:Miller.DavidJ@epa.gov>]**Sent:** Friday, April 15, 2016 9:11 AM**To:** Baker, John D; Garcia-Malene, Gorka**Subject:** RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hello John,

I do, but I just haven't had a chance to send it yet. We've been focusing on the Powerpoint presentation and what we wanted to discuss with you which is pretty much done now. So it become easier to do the agenda/discussion topics now. Basically, we will have three parts: 1) spot-on issue: where we are and what we've done; 2) case study of Seresto collar; and 3) FDA thoughts on spreadsheet/template.

More later (today) ... including an agenda ! Sorry for the delays.

Finally, we are making arrangements to carpool there and arrive a bit before 10 am. I envision a roughly two hour meeting ... with our part being an hour.

David.

From: Baker, John D [<mailto:John.Baker@fda.hhs.gov>]**Sent:** Friday, April 15, 2016 8:51 AM**To:** Miller, David <Miller.DavidJ@epa.gov>; Garcia-Malene, Gorka <Gorka.Garcia-Malene@fda.hhs.gov>**Cc:** Baker, John D <John.Baker@fda.hhs.gov>**Subject:** RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Good morning David,

Any progress on the agenda?

We can provide a summary of our pharmacovigilance program if you think it would be helpful.

How much time do you think you will need for your presentation?

After the presentations, we can have a discussion regarding your Spot-on spreadsheet.

Thank you very much,
John

From: Miller, David [<mailto:Miller.DavidJ@epa.gov>]**Sent:** Thursday, April 14, 2016 11:36 AM**To:** Baker, John D; Garcia-Malene, Gorka

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Will do. And I still owe you an agenda. Had planned on getting this to you last night, but didn't.

From: Baker, John D [<mailto:John.Baker@fda.hhs.gov>]

Sent: Thursday, April 14, 2016 8:34 AM

To: Garcia-Malene, Gorka <Gorka.Garcia-Malene@fda.hhs.gov>; Miller, David <Miller.DavidJ@epa.gov>

Cc: Baker, John D <John.Baker@fda.hhs.gov>

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Good morning David,

Please give me a call (240-402-5835) when you arrive and I will meet your group in the lobby of 7519.

Thanks,
John

From: Garcia-Malene, Gorka

Sent: Wednesday, April 13, 2016 3:59 PM

To: Baker, John D; Miller, David

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi David,

Do keep John's office phone number when you arrive here in the event the guards need to call him down during the sign-in process.

Thanks,
Gorka

From: Baker, John D

Sent: Wednesday, April 13, 2016 2:41 PM

To: Miller, David; Garcia-Malene, Gorka

Cc: Rossmeisl, Colleen; Breeden, Julie; Davis, Kable; Echeverria, Marietta; Nguyen, James; Sarkar, Bayazid; Evans, Elizabeth; Recore, Shanna; Baker, John D

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi David,

We look forward to receiving your agenda input and we can discuss tomorrow.

Here is our address for your GPS:

7519 Standish Place (Building MPN-2)
Rockville, MD 20855

Our security personnel will review your EPA badges and/or we can have you sign in as needed.

We look forward to seeing you at 10am on Monday, April 18th.

Thanks,
John

John D. Baker, DVM
Director, HFV-240
Division of Veterinary Product Safety
Office of Surveillance and Compliance
FDA, Center for Veterinary Medicine
john.baker@fda.hhs.gov
240-402-5835
240-276-9193 (fax)

From: Miller, David [<mailto:Miller.DavidJ@epa.gov>]
Sent: Wednesday, April 13, 2016 2:15 PM
To: Baker, John D; Garcia-Malene, Gorka
Cc: Rossmeisl, Colleen; Breeden, Julie; Davis, Kable; Echeverria, Marietta; Nguyen, James; Sarkar, Bayazid; Evans, Elizabeth; Recore, Shanna
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hello John and Gorka,

I got your voicemail yesterday. Let us draft up a few thoughts with respect to an agenda and objectives and send them your way tonight. Perhaps we can talk tomorrow.

I know when we originally spoke a number of weeks ago, you told me where you were at – and it wasn't White Oak, Hyattsville, or College Park (and I don't think it was at Parklawn) . Could you please send that information in an email? I think we will likely plan on carpooling over there.

I've cc'd the folks here who might be attending – I don't know if you need to put them on a list for your security folks . They will all have government (US EPA) badges.

Thanks.

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)
Visit www.epa.gov/pesticides

From: Baker, John D [<mailto:John.Baker@fda.hhs.gov>]
Sent: Tuesday, April 12, 2016 3:13 PM
To: Garcia-Malene, Gorka <Gorka.Garcia-Malene@fda.hhs.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Baker, John D <John.Baker@fda.hhs.gov>
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Thanks Gorka!

We can provide the EPA an overview of our pharmacovigilance program and let them present an overview of their program and also share the details regarding the Pet Spot On products adverse event data analysis project.

I will give David a call to discuss this approach and to develop a draft agenda.

Thanks,
John

From: Garcia-Malene, Gorka
Sent: Tuesday, April 12, 2016 7:39 AM
To: Miller, David; Baker, John D
Subject: Re: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Good morning John,

Based on this email and our conversation yesterday, I understand that the scope of the upcoming meeting has changed and will not involve Confidential Commercial Information, Trade Secrets, or Personal Privacy Information held by FDA. Instead, your Division plans to share materials already cleared for public disclosure. Consequently, I no longer see the need to put in place an FDA information exchange arrangement for purposes of the April 18th meeting.

Let me know if there are any questions.

Gorka

From: Miller, David
Sent: Friday, April 8, 2016 3:00 PM
To: Baker, John D
Cc: Garcia-Malene, Gorka
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hello John,

Hopefully, the agreement thing can be worked out in time so can we meet on the 18th.

But –for an FYI – we have prepared an Excel spreadsheet template that we plan on providing to the Spot-on registrant's in early May for them to try out for a year as part of a pilot process. This would be one of the things we would be discussing with you. So... in anticipation of our meeting on the 18th, please find this spreadsheet template attached. We would appreciate any comments or suggestions you might have and feel free to share with your staff ahead of time.

Note that we have already shared this with and sought – and incorporated – input from folks at PVWorks/Assurance in the UK, from SafetyCall, from Canada's Pest Management Regulatory Agency, and the veterinary/veterinary portal folks at the National Pesticide Information Center (see <http://www.npic.orst.edu/> and <http://www.npic.orst.edu/health/pets2.html>) . We are looking to FDA/CVM to provide any additional comments or thoughts you might have. Again, we consider this to be a pilot process, so there will be opportunities for changes as we move ahead and spot-on registrants have had time to try it out.

Regards,

David.

.....
David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)
Visit www.epa.gov/pesticides

From: Miller, David
Sent: Thursday, April 07, 2016 11:59 AM
To: Baker, John D <John.Baker@fda.hhs.gov>; 'Garcia-Malene, Gorka' <Gorka.Garcia-Malene@fda.hhs.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hello again,

Please see if the attached is ok.

I note that – particularly for this first meeting and I can foresee probably for all meetings – we would not be expecting to walk away from FDA with any FDA data at all.

David

From: Davis, Kable
Sent: Thursday, April 07, 2016 11:49 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi David –

Here is the revised letter from Don. Based on the call we had this morning, he tried to characterize the purpose of our upcoming meeting. You may want to read over the first paragraph to make sure understanding of the meeting is the same as yours. If so, would you please pass this along to FDA?

Thanks much,
Bo

From: Sadowsky, Don
Sent: Thursday, April 07, 2016 10:52 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Kable –

Attached is the letter, modified along the lines we talked about in our telephone call. Please ensure that I correctly characterized what you will do with the information. I also took a paragraph that was written as if it were from the perspective of FDA and rewrote it from the perspective of EPA, since the letter is coming from EPA.

Hopefully this will resolve any differences, and obviate the need for FDA's Office of Chief Counsel to review the letter.

Let me know if you have any questions.

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. 20460
(202) 564-5638

From: Davis, Kable
Sent: Thursday, April 07, 2016 9:46 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

From: Davis, Kable
Sent: Friday, April 01, 2016 10:28 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Miller, David <Miller.DavidJ@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Knorr, Michele <Knorr.Michele@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi Don --

I hope all is well. Please see the chain of emails below. Apparently, there are issues at FDA with the EPA-proposed revisions to their letters. Would you mind looking over it and providing comment? Our meeting with FDA is scheduled for 4/18.

Thanks for your help.
Bo

From: Miller, David
Sent: Friday, April 01, 2016 10:23 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Bo,

Can you forward this on to whomever at EPA this needs to be forwarded on to.

Apparently, there are issues at FDA with the EPA-proposed revisions.

David

From: Garcia-Malene, Gorka [<mailto:Gorka.Garcia-Malene@fda.hhs.gov>]
Sent: Friday, April 01, 2016 10:08 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Baker, John D <John.Baker@fda.hhs.gov>
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Good morning All,

Attached please find my comments on EPA's draft agreement. I should mention that EPA's changes were deemed significant enough that they have been forwarded to FDA's Office of Chief Counsel for review. OCC has yet to provide comments. I'll forward those when they become available. By including my personal comments via the attached draft, my hope is that we can massage the draft sufficiently back to the original language so that OCC's review will no longer be necessary. Otherwise, this may prove to be a time intensive exercise.

Thanks,
Gorka

From: Miller, David [<mailto:Miller.DavidJ@epa.gov>]
Sent: Monday, March 28, 2016 10:20 AM
To: Garcia-Malene, Gorka; Baker, John D
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hello,

Please see below and attached and let us know if this works for you.

Also, the 18th may work out better for us -- are you all ok with this date? The 11th would be fine, too, though. Recall that I will be on travel for 10 days beginning the 21st April, so if we missed the 18th for some reason, we'd need to delay for at least a couple of weeks after that.

Tx.

David.

From: Davis, Kable
Sent: Monday, March 28, 2016 10:10 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi David --

I hope all is well. OGC had a few changes for the document FDA wants us to sign. Would you please forward this to your FDA contact and see if this version works for them? If so, I'll work on having someone sign in from EPA.

Thanks much,

Bo

From: Sadowsky, Don
Sent: Monday, March 28, 2016 9:19 AM
To: Breeden, Julie <Breeden.Julie@epa.gov>; Knorr, Michele <knorr.michele@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Here is a markup of the document. Last year we negotiated a data sharing agreement with FDA and did not like their standard language regarding sharing of the information by EPA. We negotiated an alternative version of that language with FDA, which you should include here.

Let me know if you have any questions. I can be reached at Ex. 6 PP – personal phone

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. 20460
(202) 564-5638

From: Breeden, Julie
Sent: Friday, March 25, 2016 6:51 AM
To: Knorr, Michele <knorr.michele@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Good morning

Bo asked me to follow-up on the request for OGC to review the agreement that FDA wants us (Susan Lewis) to sign before we visit. The way I read your email, Michele, is that Don returns to the office on the 28th, is this correct?

Many thanks for your assistance on this matter. Enjoy your weekend!
Julie

Julie A. Breeden, DVM
U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1
Breeden.Julie@epa.gov
Phone: 703.347.0511
Office: S-7823, Mail Code: 7505P

From: Knorr, Michele
Sent: Thursday, March 17, 2016 9:25 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities
Importance: High

Don – here is the letter developed for EPA's visit to FDA. Thanks for looking at this when you return to the office.

Bo/Julie – Don has reviewed agreements like this in the past. He will be out after today until a week from Monday. He said he could look at it at that time. I believe the visit isn't until April, so I hope that timing works for you.

Michele L. Knorr
Attorney
Pesticides and Toxics Law Office
Office of General Counsel
202-564-5631

From: Davis, Kable
Sent: Tuesday, March 15, 2016 1:55 PM
To: Knorr, Michele <knorr.michele@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi Michele –

Please see the chain of emails below. I forwarded this to Susan and she wanted me to double check with you on whether or not it's appropriate for her to sign it.

Thanks,
Bo

From: Davis, Kable
Sent: Tuesday, March 15, 2016 9:30 AM
To: Lewis, Susan <Lewis.Susan@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi Susan –

HED and RD has an upcoming meeting with FDA to discuss enhanced reporting for spot-on products and FDA wants us to sign the attached letter. David Miller assumes they need this document so they feel comfortable showing us what they have in terms of incidents for pet products. He also suggested you be the person that signs the letter. Are you comfortable with this? If so, I'll put everything into our letterhead and forward to you for signature.

Thanks much,
Bo

From: Miller, David
Sent: Tuesday, March 15, 2016 9:04 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>

Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

FYI – apparently, they want us to fill this out saying that we want access to

- The CVM Adverse Drug Event database, called “PV Works / PV Analyser”, which includes the numerous data elements defined in Form FDA 1932, and which may include Personal Privacy Information and Confidential Commercial Information

pursuant to 21 C.F.R. § 20.85:

and that this has PPI and Confidential Commercial Information.

From: Garcia-Malene, Gorka [<mailto:Gorka.Garcia-Malene@fda.hhs.gov>]

Sent: Monday, March 14, 2016 2:49 PM

To: Miller, David <Miller.DavidJ@epa.gov>

Cc: Baker, John D <John.Baker@fda.hhs.gov>

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Good Afternoon David,

Attached please find a template for the 20.85 agreement for your upcoming visit to FDA. Please complete the document as appropriate, printing it out in your agency's letterhead, and return it to us for processing.

Let me know if there are any questions.

Gorka

From: Baker, John D

Sent: Thursday, March 10, 2016 4:09 PM

To: Miller, David

Cc: Garcia-Malene, Gorka; Baker, John D

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi David,

To facilitate discussion of any MOU issues, I copied my CVM colleague, Gorka Garcia-Malene for his insight.

Also, have you determined if Monday, April 11th is a good day for your visit?

Best regards,
John

From: Miller, David [<mailto:Miller.DavidJ@epa.gov>]

Sent: Wednesday, March 09, 2016 8:01 AM

To: Baker, John D

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Dear Dr. Baker,

When we last spoke, we discussed visiting you folks up in White Oak on either Tuesday 22 February or Tuesday 29 February. I said I'd get back to you after I checked re: people availability here, with you indicating you would block off portions of both days.

This email is to let you know that Tuesday 29 February is ok with us. I am thinking perhaps we could set aside perhaps a 1 ½ block of time inside a 10 am to noon window. Would that be ok with you? I am hoping that would avoid the traffic. We would likely send you up some material in advance of this (e.g., our draft Pet Spot-on data entry spreadsheet that we'd very much appreciate your thoughts on) so you would have a chance to review it ahead of time.

I think you were going to check the EPA-FDA MOU to ensure that FDA would be able to do this. You didn't think that there would be a problem. Did it turn out that way and thus we are all set in that regard?

Again, we look forward to meeting with you and your team.

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)
Visit www.epa.gov/pesticides

From: Miller, David
Sent: Friday, March 04, 2016 3:24 PM
To: 'John.Baker@fda.hhs.gov' <John.Baker@fda.hhs.gov>
Subject: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Dear Dr. Baker,

My name is David Miller and I am a branch chief in the US Environmental Protection Agency's Office of Pesticide Programs of a branch which deals with post-marketing surveillance and toxicovigilance issues associated with pet products. As you may know, the US EPA is responsible for regulating pet spot-on products, and we are currently re-looking at pet incidents associated with these products.

By way of background, we originally began looking at spot-on incidents several years ago, with information and background on this work available at: <http://www.epa.gov/pets> and <http://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects>. Note that this information is current as about 5 or 6 years ago, based on what we knew then and does not reflect current activities. One of the outcomes of this initial look of several years ago was to require the spot-on manufacturers (aka pesticide registrants) to submit to the Agency enhanced pet incident reports on a quarterly basis.

We now have about 5 years worth of enhanced reporting information and have developed thoughts on ways to go about analyzing and interpreting the data. Given the CVM's Division of Product Safety more extensive experience with this kind of information, we would like to meet with you to discuss where we are at and any suggestions you might have with respect to our activities in this area. To the extent that we at EPA follow similar practices to those of FDA/CVM (e.g, use of VedDRA terms, signal detection techniques and thresholds, etc.), this would probably be a good thing. To the extent we may differ, it would be good for us to be knowledgeable about why and where there are difference and be able to provide appropriate rationale. I note that we have conversed over the last several weeks with Rick Kingston of Safety Call and with Assure, the makers of PV-Works pharmacovigilance software (which we understand FDA's CVM makes extensive use of).

Is meeting with us something you would be willing and able to do sometime during the month of March? If you like, we would be willing to visit you to review where we are at and what we are thinking. We plan on meeting with the representatives from the Animal Health Institute (AHI) sometime after that as well as making available our data template and plans as part of a 90-day public comment period over the summer.

Thank you for any assistance you may be able to provide.

Regards,

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)
Visit www.epa.gov/pesticides

Message

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 5/5/2016 2:08:03 PM
To: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]
Subject: RE: update regarding spot-ons and seresto

Oops. I set my alarm for 6:30, turned it off, and overslept until 9:30.

Just in now.

David.

From: Rossmeisl, Colleen
Sent: Thursday, May 05, 2016 10:02 AM
To: Recore, Shanna <Recore.Shanna@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>
Subject: RE: update regarding spot-ons and seresto

Hi all -

Sorry I missed the meeting - I had already had leave scheduled this morning and just got in (was hoping it wasn't going to take that long and would make it to the meeting, but not so...).

Shanna - if you are available I can stop by for an update or if anyone has questions for me let me know.

Thanks!
Colleen

-----Original Appointment-----

From: Recore, Shanna
Sent: Tuesday, May 03, 2016 10:17 AM
To: Miller, David; Evans, Elizabeth; Davis, Kable; Echeverria, Marietta; Nguyen, James; Sarkar, Bayazid; Breeden, Julie; Rossmeisl, Colleen
Subject: update regarding spot-ons and seresto
When: Thursday, May 05, 2016 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS10771/Potomac-Yard-One

Let's meet for an update on where we are and next steps for spot-ons and Seresto.

Message

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 4/20/2016 11:29:55 AM
To: Breeden, Julie [Breeden.Julie@epa.gov]
CC: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]
Subject: RE: Timeline for pilot template

The FDA CVM folks indicated that they would meet among themselves separately to review the template and get back to us by the end of the first week in May. I will be back from China at the beginning of the first week in May. So – assuming they don't have drastic changes – I would assume that we could get it out during the second week in May.

Separately:

Presumably – after bringing the issue of with Susan L. and perhaps a bit of digging here – you folks will likely want to give a heads up to FEAD on PMRA's Seresto situation. We probably want to remain in close communication with PRMA on this so we aren't blindsided. Shanna is keeping a close ear to the ground with PMRA on this.

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Breeden, Julie
Sent: Wednesday, April 20, 2016 7:19 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: Timeline for pilot template

Good morning David,

The organization/development of the communication strategy with FEAD continues regarding the pet spot-on enhanced reporting pilot. Post FDA-CVM meeting, have you an idea of a timeline by which the template will be ready for public release?

Many thanks,
Julie

Julie A. Breeden, DVM

U.S. Environmental Protection Agency

OCSP / OPP / RD / IVB1

Breeden.Julie@epa.gov

Phone: 703.347.0511

Office: S-7823, Mail Code: 7505P

Message

From: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
Sent: 5/16/2016 1:31:49 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]
CC: Davis, Kable [Davis.Kable@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Seresto companion animal studies

Yes, I was thinking it would be good to have a better handle on it before that meeting. If we want to meet next week to discuss current status of what we know, I think I can have an overview of what my impressions are by then. Just FYI, I am out most of the week of May 31 - June 2.

I assume we haven't heard anything else from PMRA at this point?

Thanks -
Colleen

From: Miller, David
Sent: Monday, May 16, 2016 9:07 AM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; Breeden, Julie <Breeden.Julie@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Re: Seresto companion animal studies

thanks. This is useful. Recall that we will be meeting with Bayer in early June, so it would be good if we could have a good idea of this by then, if possible.

From: Rossmeisl, Colleen
Sent: Monday, May 16, 2016 7:44 AM
To: Recore, Shanna
Cc: Miller, David; Davis, Kable; Breeden, Julie; Echeverria, Marietta
Subject: Seresto companion animal studies

Hi Shanna (and others) -

Just wanted to let you know I am still looking over the companion animal studies in light of the incident data reported for Seresto.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Still going through the additional studies as well. I will keep you posted.

Thanks!

Colleen

Message

From: Bright, Susan [Susan.Bright@fda.hhs.gov]
Sent: 5/17/2016 8:11:03 PM
To: Miller, David [Miller.DavidJ@epa.gov]
CC: Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]
Subject: RE: Questions from FDA/CVM

Thank you David! I will forward the e-mail inquiry about Seresto to Julie and Colleen shortly, and cc you. If Liz and Shanna need further information about the Activyl report, let me know. We look forward to further interactions with your group!

Regards,

Susan

Susan J. Bright-Ponte, DVM, MPH

Team Leader, HFV-243
Data Management and Analysis Team
Division of Veterinary Product Safety
Office of Surveillance and Compliance
FDA, Center for Veterinary Medicine
7519 Standish Place, Room 2627
Rockville, MD 20855
(240) 402-5777
Susan.bright@fda.hhs.gov

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, May 16, 2016 9:45 AM
To: Bright, Susan
Cc: Breeden, Julie; Rossmeisl, Colleen; Davis, Kable; Echeverria, Marietta; Evans, Elizabeth; Recore, Shanna
Subject: Re: Questions from FDA/CVM

Hello Susan,

Thanks for your email.

With respect to data/statistical analysis, we'd be happy to discuss these things with you and CVM as we move along. The Bayer Seresto folks have requested a (first time) in-person meeting with us during early June for , so we will likely be sharing with them what we shared with you when we visited.

With respect to the first of your questions, feel free to forward the email from NCSU to Julie Breeden and Colleen Rossmeisl (both vets) with a cc: to me. I am not sure exactly how we typically handle these kinds of queries (I don't think we typically receive these) so it would be good for us to internally discuss this. We are mostly set up to receive concerns, not so much to offer feedback or provide data.

With respect to your second question, I have forwarded this to Elizabeth Evans and Shanna Recore who will look into it and we will discuss this internally. Typically, this would enter the database and we would review

these when the active ingredient came up for registration review. This would be the normal course of events unless the folks responsible for the database felt that it needed to be dealt with immediately in which case it would come to us (generally Liz Evans and Shanna Recore). Of course, if FDA receives something directly and has a question or concern, feel free to contact us directly.

david.

From: Bright, Susan <Susan.Bright@fda.hhs.gov>

Sent: Monday, May 16, 2016 9:13 AM

To: Miller, David

Subject: Questions from FDA/CVM

Hi David,

I was in the meeting with you all when EPA came to visit CVM recently, and also on the follow-up phone call the other day. I hope that your efforts at setting up a reporting system are proceeding as you'd like! We at CVM are certainly glad to be of any further assistance. I especially am interested in the data/statistical analysis side of things so would be happy to discuss any further thoughts about that as needed.

Question 1:

We received an e-mail inquiry from a clinical veterinary pharmacy resident at North Carolina State University College of Veterinary Medicine. She has questions regarding adverse events reported for Seresto. Specifically she is asking if diarrhea is a reported adverse event for Seresto collars in dogs.

May I forward her e-mail to you, or someone in your office to handle her inquiry? Or is there some other way you'd like me to handle it?

Question 2:

A while back we had received an adverse event report for Activyl (dog product) Spot-On used on a cat. The adverse event was neurologic signs and seizures; the cat did recover. We did forward the report on to you as usual. I had meant to contact someone at EPA about the report because the reporter's complaint was that the inner packaging for Activyl was confusing/not clear that the product was for dogs. Apparently the outer box has a picture of a cat or dog, but the blister packs the pipettes come in may not be clearly labeled with species? Apparently the owner had not saved the boxed, just the blister packs. I don't know what the Activyl blister packs look like, so am not sure of the validity of the complaint, but I just wanted to pass it on to you folks, as I guess if the packaging is not clear, it could lead to other medication errors like this. This report came in a few months ago I think- sorry I did not reach out sooner- I had put it on the back-burner and it stayed there longer than it should have.

Thanks very much!

Susan

Susan J. Bright-Ponte, DVM, MPH

Team Leader, HFV-243

Data Management and Analysis Team

Division of Veterinary Product Safety

Office of Surveillance and Compliance

FDA, Center for Veterinary Medicine

7519 Standish Place, Room 2627

Rockville, MD 20855

(240) 402-5777

Susan.bright@fda.hhs.gov

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 5/17/2016 10:34:01 AM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Yep – I invited them.

From: Echeverria, Marietta
Sent: Monday, May 16, 2016 8:08 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Let's make sure PRD is looped in. Thanks.

From: Davis, Kable
Sent: Wednesday, May 11, 2016 8:22 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: FW: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Hi David and Marietta –

Bayer is asking for a meeting regarding Seresto. They would like a status of our review and an understanding of the intent. I don't mind scheduling the meeting, however will be in position to provide that information by early June?

Thanks much,
Bo

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Wednesday, May 11, 2016 8:13 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Dear Mr. Davis,
Bayer HealthCare, Animal Health Division, is requesting a meeting with the Agency regarding the subject product.

The purpose of the meeting is for:

1. The Agency to provide us with an update regarding its current review of the incident data and other information we provided
2. Bayer to provide a brief overview of our interpretation of the information
3. The Agency to provide Bayer with an understanding of the Agency's intentions and next steps

We therefore, request that you schedule a 1-1/2 hour meeting with the appropriate members of the Agency for an effective discussion.

We suggest a convenient time on either June 2 or June 8th.

Attending from Bayer HealthCare will be:

- Robert Zolynas, Head of Global Development

- Bruce Martin, Director of Regulatory Affairs
- Douglas Spilker, Manager of EPA Regulatory Affairs
- Will Heeb, Manager of Pharmacovigilance
- Jessica Monachello, Bayer General Legal Council
- Roger Martella, Sidley Austin LLP

Please let us know as soon as possible so we can make appropriate travel plans.

Best Regards,

Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs

Bayer Animal Health
Bayer HealthCare LLC
P.O. Box 390
Shawnee Mission, KS 66201-0390
USA

Office: +1 -913-268-2751
Mobile: +1 -816-506-3102
Email: doug.spilker@bayer.com

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Appointment

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 5/24/2016 8:36:18 PM
To: Recore, Shanna [Recore.Shanna@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Britton, Wade [Britton.Wade@epa.gov]; VanAlstine, Julie [VanAlstine.Julie@epa.gov]; Hawkins, Monica [Hawkins.Monica@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
CC: Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]
Subject: Update -- and Discuss upcoming spot-on and Seresto activities and meetings
Attachments: Agenda and Notes from 5_13_16 Kingston meeting.docx
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/25/2016 12:30:00 PM
End: 5/25/2016 1:30:00 PM
Show Time As: Tentative

Required Attendees: Recore, Shanna; Sarkar, Bayazid; Evans, Elizabeth; Rossmeisl, Colleen; Breeden-Alemi, Julie; Echeverria, Marietta; Nguyen, James; Davis, Kable; Britton, Wade; VanAlstine, Julie; Hawkins, Monica; Davis, Donna
Optional Attendees: Adler, Bonnie; Biscoe, Melanie; Arrington, Linda

See agenda and notes from Rick Kingston meeting attached

David.



Agenda and Notes
from 5_13_16 Ki...

P.S. I promise not to oversleep this meeting ; -)

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 5/24/2016 8:01:22 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: FW: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Bayer just confirmed that they are bringing their legal counsel with them to the upcoming Seresto meeting.

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Tuesday, May 24, 2016 4:00 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Subject: Re: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Yes, we are bringing legal Counsel.

Douglas A. Spilker, Ph. D.
Bayer Animal Health

This message may be brief since it was sent from my iPhone (816-506-3102). Office #913-268-2751.

On May 24, 2016, at 3:32 PM, Davis, Kable <Davis.Kable@epa.gov> wrote:

Hi Doug –

I just wanted to confirm that you are in fact bringing your legal counsel with you to this meeting. According to your email below, it sounds as though you are. There isn't a reason for me to have OGC attend, if I misunderstood.

Thanks much,
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Wednesday, May 11, 2016 8:13 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Seresto (PNR 1427 Insecticide; EPA Reg. No.11556-155); Request for Update Meeting

Dear Mr. Davis,
Bayer HealthCare, Animal Health Division, is requesting a meeting with the Agency regarding the subject product.

The purpose of the meeting is for:

1. The Agency to provide us with an update regarding its current review of the incident data and other information we provided
2. Bayer to provide a brief overview of our interpretation of the information
3. The Agency to provide Bayer with an understanding of the Agency's intentions and next steps

We therefore, request that you schedule a 1-1/2 hour meeting with the appropriate members of the Agency for an effective discussion.

We suggest a convenient time on either June 2 or June 8th.

Attending from Bayer HealthCare will be:

- Robert Zolynas, Head of Global Development
- Bruce Martin, Director of Regulatory Affairs
- Douglas Spilker, Manager of EPA Regulatory Affairs
- Will Heeb, Manager of Pharmacovigilance
- Jessica Monachello, Bayer General Legal Council
- Roger Martella, Sidley Austin LLP

Please let us know as soon as possible so we can make appropriate travel plans.

Best Regards,

Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs

Bayer Animal Health
Bayer HealthCare LLC
P.O. Box 390
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Office: +1 -913-268-2751
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Email: doug.spilker@bayer.com

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Message

From: Biscoe, Melanie [Biscoe.Melanie@epa.gov]
Sent: 5/25/2016 5:39:41 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Knorr, Michele [knorr.michele@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]
CC: Arrington, Linda [Arrington.Linda@epa.gov]
Subject: RE: Internal Seresto Meeting

I forwarded this invitation to Linda Arrington, Branch Chief for Seresto in PRD.

Melanie Biscoe

Team Leader, Risk Management and Implementation Branch V
Pesticide Re-evaluation Division
Office of Pesticide Programs, US EPA
biscoe.melanie@epa.gov
703-305-7106

-----Original Appointment-----

From: Davis, Kable
Sent: Wednesday, May 25, 2016 12:21 PM
To: Davis, Kable; Echeverria, Marietta; Miller, David; Knorr, Michele; Breeden-Alemi, Julie; Biscoe, Melanie; Adler, Bonnie
Subject: Internal Seresto Meeting
When: Tuesday, June 07, 2016 3:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS7671C/Potomac-Yard-One

Michele –

We have a few questions for you concerning the upcoming meeting with Bayer (6/9/16) concerning Seresto. Below is the call-in information.

Call-in No: Ex. 6 PP - conference code/call in number
Conf. Code:

Appointment

From: Recore, Shanna [Recore.Shanna@epa.gov]
Sent: 5/3/2016 2:28:20 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
CC: Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]

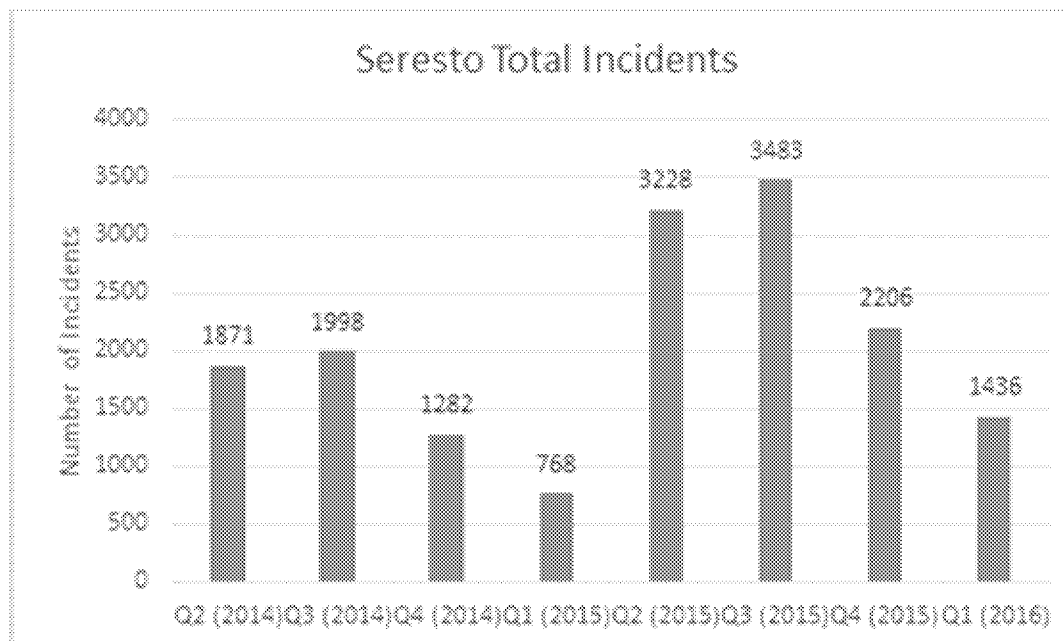
Subject: update regarding spot-ons and seresto
Attachments: ATT90213; ATT28945
Location: DCRoomPYS10771/Potomac-Yard-One

Start: 5/5/2016 1:00:00 PM
End: 5/5/2016 2:00:00 PM
Show Time As: Tentative

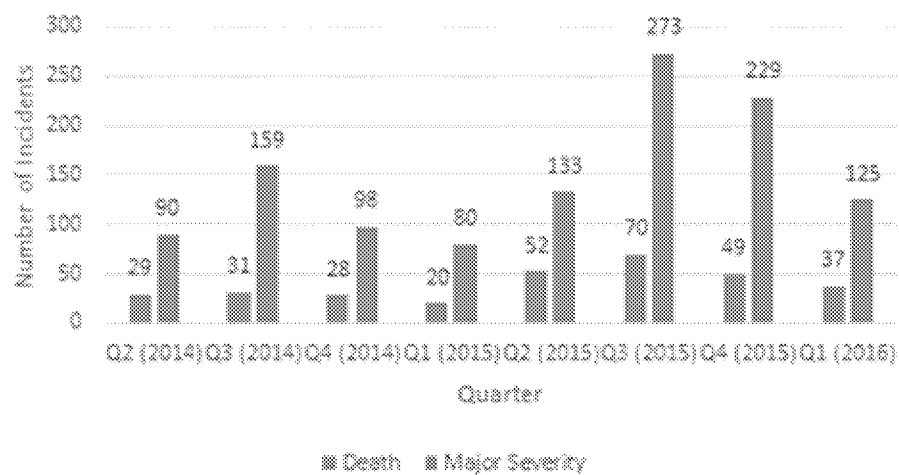
Required Attendees: Miller, David; Evans, Elizabeth; Davis, Kable; Echeverria, Marietta; Nguyen, James; Sarkar, Bayazid; Breeden, Julie;
Optional Attendees: Rossmeisl, Colleen
Optional Attendees: Arrington, Linda; Biscoe, Melanie; Adler, Bonnie

Let's meet for an update on where we are and next steps for spot-ons and Seresto.

Here is a look at the seasonal trend for Seresto with the new FY16 Q1 incidents



Seresto Death and Major Severity by Quarter



Message

From: Evans, Elizabeth [Evans.Elizabeth@epa.gov]
Sent: 5/25/2016 5:43:20 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Britton, Wade [Britton.Wade@epa.gov]; VanAlstine, Julie [VanAlstine.Julie@epa.gov]; Hawkins, Monica [Hawkins.Monica@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
CC: Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]
Subject: RE: Update -- and Discuss upcoming spot-on and Seresto activities and meetings
Attachments: Safety Call Incident Scoring pulled from Sergeants' conditional registrant report _ Appendix IV.docx

Attached is the Scoring of incidents written up by SafetyCall that is found on page 330 of the Sergeant's enhanced data report- Appendix IV.

This scoring system is the same concept as assigning case causality. This scoring system was brought up in our meeting this morning.



Safety Call
Incident Scoring ...

From: Miller, David
Sent: Wednesday, May 25, 2016 12:18 PM
To: Recore, Shanna <Recore.Shanna@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Britton, Wade <Britton.Wade@epa.gov>; VanAlstine, Julie <VanAlstine.Julie@epa.gov>; Hawkins, Monica <Hawkins.Monica@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Adler, Bonnie <Adler.Bonnie@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Arrington, Linda <Arrington.Linda@epa.gov>
Subject: RE: Update -- and Discuss upcoming spot-on and Seresto activities and meetings

<< File: Spot On Seresto slides for FDA meeting 4-18-16_send_update.pptx >>

All,

There are several things we said we'd send out. These will need to go in pieces over today. But here's the first -- the

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

So, decisions will need to be made on that.

But the attached may help in understanding some of the other stuff that was done, beyond what we spoke about today.

David.

-----Original Appointment-----

From: Miller, David

Sent: Sunday, May 22, 2016 5:39 PM

To: Miller, David; Recore, Shanna; Sarkar, Bayazid; Evans, Elizabeth; Rossmeisl, Colleen; Breeden-Alemi, Julie; Echeverria, Marietta; Nguyen, James; Davis, Kable; Britton, Wade; VanAlstine, Julie; Hawkins, Monica; Davis, Donna

Cc: Adler, Bonnie; Biscoe, Melanie; Arrington, Linda

Subject: Update -- and Discuss upcoming spot-on and Seresto activities and meetings

When: Wednesday, May 25, 2016 8:30 AM-9:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomPYS10771/Potomac-Yard-One

See agenda and notes from Rick Kingston meeting attached

David.

<< File: Agenda and Notes from 5_13_16 Kingston meeting.docx >>

P.S. I promise not to oversleep this meeting ; -)

Message

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 5/25/2016 4:27:48 PM
To: Recore, Shanna [Recore.Shanna@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Britton, Wade [Britton.Wade@epa.gov]; VanAlstine, Julie [VanAlstine.Julie@epa.gov]; Hawkins, Monica [Hawkins.Monica@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
CC: Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]
Subject: RE: Update -- and Discuss upcoming spot-on and Seresto activities and meetings
Attachments: NYT Federal Audit Finds Broad Failures at NHTSA.pdf; OIG INADEQUATE DATA AND ANALYSIS UNDERMINE NHTSA'S EFFORTS TO IDENTIFY AND INVESTIGATE VEHICLE SAFETY CONCERNS.pdf; New Yorker. The Engineer's Lament.pdf

Also, some of you have already seen this as I have circulated this before (and TEB folks will probably groan at seeing this again), but I attach a couple an article form NYT and the OIG report that I circulated before. This concerns NHTSA and their signal detection system (or lack thereof)



NYT Federal Audit
Finds Broad Fail...



OIG INADEQUATE
DATA AND ANAL...

I also attach one that Rick Kingston shared with us:



New Yorker. The
Engineer's Lame...

David

From: Miller, David
Sent: Wednesday, May 25, 2016 12:17 PM
To: Recore, Shanna <Recore.Shanna@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Britton, Wade <Britton.Wade@epa.gov>; VanAlstine, Julie <VanAlstine.Julie@epa.gov>; Hawkins, Monica <Hawkins.Monica@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Adler, Bonnie <Adler.Bonnie@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Arrington, Linda <Arrington.Linda@epa.gov>
Subject: RE: Update -- and Discuss upcoming spot-on and Seresto activities and meetings

<< File: Spot On Seresto slides for FDA meeting 4-18-16_send_update.pptx >>

All,

There are several things we said we'd send out. These will need to go in pieces over today. But here's the first -- the

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) So, decisions will need to be made on that.

But the attached may help in understanding some of the other stuff that was done, beyond what we spoke about today.

David.

-----Original Appointment-----

From: Miller, David

Sent: Sunday, May 22, 2016 5:39 PM

To: Miller, David; Recore, Shanna; Sarkar, Bayazid; Evans, Elizabeth; Rossmeisl, Colleen; Breeden-Alemi, Julie; Echeverria, Marietta; Nguyen, James; Davis, Kable; Britton, Wade; VanAlstine, Julie; Hawkins, Monica; Davis, Donna

Cc: Adler, Bonnie; Biscoe, Melanie; Arrington, Linda

Subject: Update -- and Discuss upcoming spot-on and Seresto activities and meetings

When: Wednesday, May 25, 2016 8:30 AM-9:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomPYS10771/Potomac-Yard-One

See agenda and notes from Rick Kingston meeting attached

David.

<< File: Agenda and Notes from 5_13_16 Kingston meeting.docx >>

P.S. I promise not to oversleep this meeting ; -)

Message

From: Arrington, Linda [Arrington.Linda@epa.gov]
Sent: 6/3/2016 12:26:03 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: Automatic reply: Seresto Discussion

I will be out of the office from 5/31- 6/6. Please contact Jill Bloom for assistance.

Take care

Linda

Message

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 6/9/2016 4:13:51 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Breedon-Alemi, Julie [Breedon-Alemi.Julie@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]
Subject: FW: Response to EPA's Request of October 8, 2015
Attachments: Bayer AH EPA Enhanced Reporting Communication Detail.xlsx

Ex. 5 Deliberative Process (DP)

David,

From: Sarkar, Bayazid
Sent: Thursday, June 09, 2016 11:10 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Recore, Shanna <Recore.Shanna@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>
Subject: FW: Response to EPA's Request of October 8, 2015

David,

Attached is the Bayer excel file where they listed the name of the EPA person to whom the quarterly sales information was sent.

-Bayazid

From: Miller, David
Sent: Sunday, November 01, 2015 11:41 AM
To: Recore, Shanna <Recore.Shanna@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>
Subject: FW: Response to EPA's Request of October 8, 2015

I'd spoken to a couple of you last week about using the attached to see if what we have and don't have and comparing this with what Bayer says we have and don't have.

Please have this ready in time for at least shortly before the Wednesday conference call with Bayer, as it will be a good thing to mention this to them -- what's missing and what's not. This will need to be with respect to both sales volume and with respect to incidents.

If you need Bo to help, let me know. This would be useful primarily -- I think -- in locating anything that is missing from our records.

David.

From: Miller, David
Sent: Tuesday, October 20, 2015 9:25 AM
To: Recore, Shanna <Recore.Shanna@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>
Subject: FW: Response to EPA's Request of October 8, 2015

FYI --

From: Davis, Kable
Sent: Tuesday, October 20, 2015 9:13 AM
To: Miller, David <Miller.David1@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: FW: Response to EPA's Request of October 8, 2015

Hi David --

Here is the requested information from Bayer. Let me know if you need anything else.

Enjoy your day.
Bo

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Tuesday, October 20, 2015 9:03 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: Response to EPA's Request of October 8, 2015

Dear Mr. Davis,
Please find below Bayer's response to the EPA's Email of October 8, 2015:

Summary of EPA's requested information:

[EPA requested] the following additional data for [their] analysis:

1. The Bayer data for K9 Advantix II only distinguishes deaths vs. non-deaths. We would like the K9 Advantix II incidents to be separated into deaths, major, moderate, and minor for the spot-on rather than being reported as simply deaths vs. non-deaths;

BAH: As required by the Agency for all pet spot-on products, Bayer submitted enhanced and extensive reports to EPA that contains the requested information on a quarter by quarter basis for the Advantage II and K9 Advantix II products since 1q2011. We believe the most efficient way for EPA to access this extensive information is with the submitted detailed reports. To aid EPA in that effort, please find attached a listing (Bayer AH EPA Enhanced Reporting Communication Detail.xlsx) of all the correspondence by date and the recipient of this information at the Agency. Please let us know if the Agency is unable to access this information and we will provide a flash drive to the Agency given the reports are too large to email.

2. The sales data for K9 Advantix II broken down by individual years 2013, 2014, and 2015.

BAH: Bayer has included in the enhanced reports described above sales information by quarters since 1q2011. As

indicated above, if the Agency cannot access this information please let us know and we will provide a flash drive containing the reports.

3. We would appreciate it if Bayer could confirm that our selected VeDDRA PT term does appropriately match with the symptom description which Bayer intended and provided in their spreadsheet.

BAH: Bayer did provide the appropriate PT for the clinical sign at the time of data entry. As these cases spanned a period of time beginning in 2012, multiple versions of VeDDRA were included in the cases submitted to the Agency. The link provided by the Agency referenced VeDDRA version 12 which was just implemented by EMA on 01 Oct 2015. All submitted case data was prior to that date. The discrepancy the Agency noted is in relation to the changes of the listed signs from PTs to LLTs during version updates by EMA.

Bayer agrees with the majority of the Agency's modifications to the PT. However, Bayer disagrees with three specific items (listed below) that the Agency appears to have attempted to re-classify from a general symptom to one that is associated with the application site. For these three items, we respectfully urge the Agency to use the listed Appropriate VeDDRA V12 PT term when re-classifying the Bayer listed symptom.

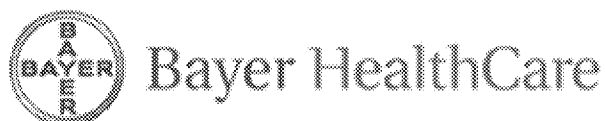
Bayer-Listed Symptom	HED-modified_symptom (VeDDRA PT)	Appropriate VeDDRA V12 PT	Total
Excoriation	Application site self trauma	Pruritus	3
Pyoderma	Application site pyoderma	Bacterial Skin Infection	82
Self Trauma	Application site self trauma	Pruritus	28

As outlined in responses to Items 1 and 2, if the Agency cannot access this information in the submitted reports, please let us know and we will provide a flash drive containing the reports.

Best Regards,
Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs
BAYER HEALTHCARE LLC
Animal Health Division
Office: 913-268-2751
Mobile: 816-506-3102
Email: doug.spilker@bayer.com

Address:
P.O. Box 390
Shawnee Mission, KS 66201-0390
Country: USA



From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: Tuesday, October 13, 2015 3:43 PM
To: Doug Spilker

Cc: Echeverria, Marietta; IVB1

Subject: RE: Response to EPA's Request of October 13, 2015

Thanks, Doug. I'll pass that along.

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Tuesday, October 13, 2015 4:42 PM
To: Davis, Kable
Cc: Echeverria, Marietta; IVB1
Subject: Response to EPA's Request of October 13, 2015

Hi Bo,

Yes, we received the request. We have people working on it but it is unlikely we will be able to reply until next week. I will try to get it to you sooner or piecemeal, but that is the only update I can give you at this time..

Best Regards,
Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs
BAYER HEALTHCARE LLC
Animal Health Division
Office: 913-268-2751
Mobile: 816-506-3102
Email: doug.spilker@bayer.com

Address:
P.O. Box 390
Shawnee Mission, KS 66201-0390
Country: USA



Bayer HealthCare

From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: Tuesday, October 13, 2015 3:31 PM
To: Doug Spilker
Cc: Echeverria, Marietta; IVB1
Subject: RE: EPA Response to Bayer letter of 28 August

Hi Doug --

I hope you had a nice holiday weekend. Please see my email below. I didn't receive a response and I wanted to make sure you received it and that it didn't fall through the cracks. Do you have an idea yet on how long it will take to provide a response? Let me know and I'll pass that information along to HED.

Enjoy the remainder of your day.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Davis, Kable
Sent: Thursday, October 08, 2015 8:41 AM
To: Doug Spilker
Cc: Echeverria, Marietta; IVB1
Subject: FW: EPA Response to Bayer letter of 28 August

Hi Doug --

I hope all is well. Please see below for HED's initial response to the information you provided on 8/28/15 concerning Seresto. HED's email provides a detailed analysis of the submission, in addition to asking for further data needed for their review. Please let me know if you have any questions. It would also be helpful if you could provide me with a timeframe for when you think you will be able to provide the additional information.

Enjoy your day.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Recore, Shanna
Sent: Thursday, October 08, 2015 8:27 AM
To: Davis, Kable
Subject: FW: EPA Response to Bayer letter of 28 August

From: Miller, David
Sent: Wednesday, October 07, 2015 5:13 PM
To: Recore, Shanna; Evans, Elizabeth; Nguyen, James; Sarkar, Bayazid
Subject: FW: EPA Response to Bayer letter of 28 August

From: Miller, David
Sent: Wednesday, October 07, 2015 5:13 PM
To: DavidJ Miller
Cc: Echeverria, Marietta
Subject: EPA Response to Bayer letter of 28 August

Bo,

Please find our responses to points raised and information provided in the Bayer Health Care letter dated 28 August 2015:

Summary of requested information:

We are requesting the following additional data for our analysis:

1. The Bayer data for K9 Advantix II only distinguishes deaths vs. non-deaths. We would like the K9 Advantix II incidents to be separated into deaths, major, moderate, and minor for the spot-on rather than being reported as simply deaths vs. non-deaths;
2. The sales data for K9 Advantix II broken down by individual years 2013, 2014, and 2015.
3. We would appreciate it if Bayer could confirm that our selected VedDRA PT term does appropriately match with the symptom description which Bayer intended and provided in their spreadsheet.

Detailed Analysis:

Seresto Sales and Incident Data, by Severity Code

- We found the Seresto sales and incident rate analysis data by severity code provided for dogs and cats for 2013, 2014, and 2015 to be adequate for our analysis.

Causality and the Weber Effect

- Bayer's letter to EPA/RD states

"The incident rate for Seresto Collars to date have followed the expected dynamics of a product launch and first years of sales. All deaths, without removals based on causality, were "very rare" in 2015 for both canine and feline. (Incidence of deaths with some probability of being caused by the product would be much lower"

and that

"the causality of the incidents have not been verified and may have causes other than exposure to the pesticides, may be associated with an underlying medical condition, and the number of cases is likely influenced by many external factors such as a new product introduction (loading of channels-in-trade), the "Weber Effect", and the ease in reporting due to the 1-800 number present on the product label"

Bayer goes on to describe the number of cases for each of four causality assessment categorizations. We note that EPA is working with PMRA to determine if causality assigned by Bayer for deaths and major severity cases are supported.

- Although Bayer Health states that the incident rates for Seresto collar have to date followed the expected dynamics given the dual and competing effects of product (pipeline) loading and the hypothesized putative Weber effect, we believe that the data provided are inadequate at this time to support this statement. Regardless, we believe that these effects, if present, will likely be mitigated in the near future and anticipate continuing this exploratory analysis in the coming months as additional incident data is accumulated by Bayer. While Bayer Health has provided reference material in support of the Weber effect to the Agency, the Agency is also aware of material that discounts this effect^[1] in

^[1] See The Weber Effect and the United States Food and Drug Administration's Adverse Event Reporting System (FAERS): Analysis of Sixty-Two Drugs Approved from 2006 to 2010 ; Drug Saf. 2014; 37(4): 283–294

which the authors conclude that “most of the modern adverse event reporting into FAERS does not follow the pattern described by Weber.” More specifically, the authors of this publication state that

Drug Safety's acceptance and publication of this study is a major milestone in AdverseEvents' mission to unravel the misinformation that has built up around the FAERS dataset. For far too long, these data have been vastly underutilized due to a lack of understanding and a general distrust over what these data can and cannot do. Clinical trials are so limited in scope that the true safety profile of a particular drug can only be determined once it reaches the public market. Therefore, the only way to fully review a drug's safety is to track and monitor side effects as the general population begins utilizing the drugs on an ongoing basis in real world circumstances. Debunking the 'Weber Effect' is only our first step in the process of redefining the dogmatic – and, we believe, incorrect – limitations that the drug safety industry assumes and assigns to these data.

And although Bayer attempted to demonstrate ‘Weber Effect’ for ‘Seresto’ by comparing this to K9 Advantix II, Bayer did not provide adequate information. To the extent that Bayer wishes to advance the Weber effect as an putative explanation for the observed incident rates for the Seresto collar, we would ask Bayer to demonstrate ‘Weber Effect’ for ‘Advantix II’ or some similar products which will assist the Agency in any risk management decision. Specifically, Bayer would need to demonstrate that incident rates of a similar product at market introduction were high and subsequently declined and stabilized over the first several years. Nevertheless, EPA at this time is taking no position on the veracity of the Weber effect but acknowledges that the Seresto collar incident rates (expressed on an incidents per units sold basis) for the most recent 6 month period ended 30 June 2015 appear to be substantially reduced compared to the earlier 2013 and 2014 years and it is these more recent rates which are likely most relevant to any risk management decision going forward

- EPA would like to note that the occurrence of the Weber effect would not impact our causality review of the reported incidents. While it may impact disproportionality of reporting, it does not indicate that the incidents 1) did not occur, 2) were not caused by the product or, 3) do not indicate a potential risk. As stated above, EPA is working with PMRA to determine causality of the reported incidents.

Seresto vs. Advantix II Analysis

- Bayer reports that the incidents associated with the Seresto collar were benchmarked against AEs associated with canines being treated with K9 Advantix II and concluded that the Seresto collar was not substantially different from the K9 Advantix II with respect to the rate of AE occurrence. The scope of the analysis for the Seresto collar included large and small dogs from the 2 ½ year period from 01 January 2013 through 30 June 2015 while the scope of the analysis for K9 Advantix II included small, medium, large, and extra-large dogs over the 4 year period from 01 January 2011 through 31 December 2014. We note that the Bayer analysis only looked at deaths vs. non-deaths. We would like the incidents to be separated into deaths, major, moderate, and minor for the two collars rather than being reported as simply deaths vs. non-deaths. We also asked Bayer to provide us the sales data for K9 Advantix II for (individual) years 2013, 2014, and 2015.

Additional Comments on Symptom Data Provided

- EPA has reviewed the incident data provided by Bayer Health in its Excel spreadsheet.
 - As acknowledged by Bayer, the symptoms were “rolled up”, being reported in a single Symptom-Onset-Duration field. While the Bayer database was substantially cleaner than many other databases we have received of this type, there were a number of database problems that we ran into. Specifically, the dash (“-”) separator was also used as a hyphen (as in “multi-organ” or “acid-base”). In addition, the Bayer use of the semicolon (“;”) separator was inconsistent, being sometimes preceded, followed, or both preceded and followed by a space which also caused us problems. Finally, “spaces” or “blanks” seemed to differ at random and appeared at times to be reflected by different unprinted ASCII characters which complicated our analysis. We might recommend in the future that tildes (“~”) or other less common typographical characters be

used as a separator and that Bayer be more internally consistent regarding spacings being particularly aware that spaces can be represented by a number of different ASCII characters.

- We note that most – but not all -- of the “Symptom” terms in the Bayer Excel spreadsheet reflect standard VedDRA vocabulary. The Agency merged the Bayer-provided symptom data with standardized VedDRA terminology data available at the Eudravigilance website (see http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/12/WC500017752.xls) in an attempt to better standardize terminology. After doing so, we noted that Bayer seems to have used primarily the VedDRA “Preferred Term” (PT) to describe symptoms. While this was generally consistent, there were several minor exceptions to this in the Bayer data; the Agency modified these in order to allow linkage to the proper VedDRA Symptom-Organ-Class (SOC) category for us to better evaluate potential symptom patterns, commonalities, and counts. As part of this activity, a variety of Bayer terms describing symptoms were changed by EPA to the VedDRA standard PT terms because the Bayer-provided term differed. For reference, these changes are presented in that attached PDF document. We would appreciate it if Bayer could review this cross-tabulation and confirm that our selected VedDRA PT term does appropriately match with the symptom description which Bayer intended and provided in their aforementioned spreadsheet. This information was used by EPA to develop a count of PT symptoms and (properly) categorize these into SOC codes.
- Regarding VedDRA PT terms and proper SOC categorization, there appeared to be some additional (general) inconsistencies in how Bayer reported their symptom terms. For example, Bayer sometimes reported the PT equivalent of “Self Trauma”, but the narrative seemed to apply that the proper term would have been “Application site self Trauma.” Similarly, hair loss was sometimes indicated to be hair loss at the application site when the narrative description did not describe it that way or instead was described as (presumably generalized) hair loss when the narrative description seemed to indicate that this occurred at the application sites. Since the VedDRA vocabulary differentiates these in terms of SOC class (e.g., “Application Site Disorders” if the hair loss occurs at the application site vs. “Skin and Appendage Disorders” if it does not), it would be preferable for the Bayer VedDRA classifications to remain true to the narrative description as much as possible when this information is known.

Note that we are not asking Bayer at this time to make these database changes (our statisticians have already done this), but note that Bayer may want to keep the above in mind for the future. Nevertheless, we do commend Bayer for providing to us a database which is generally cleaner and more easily handled than EPA typically receives.

¹ See The Weber Effect and the United States Food and Drug Administration’s Adverse Event Reporting System (FAERS): Analysis of Sixty-Two Drugs Approved from 2006 to 2010 ; Drug Saf. 2014; 37(4): 283–294

David.

.....
David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 6/9/2016 1:40:42 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Knorr, Michele [knorr.michele@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]; Hawkins, Monica [Hawkins.Monica@epa.gov]; Britton, Wade [Britton.Wade@epa.gov]; Backus, Byron [Backus.Byron@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Bloom, Jill [Bloom.Jill@epa.gov]
CC: Nguyen, James [Nguyen.James@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]
Subject: RE: Meeting with Bayer; Seresto

Everyone –

Bayer thinks their presentation should last ~20 minutes and they would like to go first.

Thanks,
Bo

-----Original Appointment-----

From: Davis, Kable
Sent: Wednesday, May 11, 2016 11:01 AM
To: Davis, Kable; Echeverria, Marietta; Miller, David; Knorr, Michele; Breeden-Alemi, Julie; Biscoe, Melanie; Adler, Bonnie; Rossmeisl, Colleen; Recore, Shanna; Davis, Donna; Hawkins, Monica; Britton, Wade; Backus, Byron; Arrington, Linda; Bloom, Jill
Cc: Nguyen, James; Sarkar, Bayazid
Subject: Meeting with Bayer; Seresto
When: Thursday, June 09, 2016 3:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS7100/Potomac-Yard-One

This time-slot worked for the majority of people.

Bayer has requested a meeting to discuss the status of review for the submitted Seresto incidents. Below is their agenda (copied and pasted):

“Bayer HealthCare, Animal Health Division, is requesting a meeting with the Agency regarding the subject product.

The purpose of the meeting is for:

- 1. The Agency to provide us with an update regarding its current review of the incident data and other information we provided***
- 2. Bayer to provide a brief overview of our interpretation of the information***
- 3. The Agency to provide Bayer with an understanding of the Agency’s intentions and next steps***

Attending from Bayer HealthCare will be:

- Robert Zolynas, Head of Global Development***
- Bruce Martin, Director of Regulatory Affairs***
- Douglas Spilker, Manager of EPA Regulatory Affairs***
- Will Heeb, Manager of Pharmacovigilance***
- Jessica Monachello, Bayer General Legal Council***

- ***Roger Martella, Sidley Austin LLP***

I'll be sure to add any presentation or agenda items prior to the meeting. Let me know if I should invite others.

Michele – I sent you an invite, since it looks like they are bringing their legal counsel.

Call-in No:

Conf. Code

Ex. 6 PP - conference code/call in number

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/3/2016 11:30:40 AM
To: Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Agenda 8/3/16 - Pyrethroid Team Meeting

Hi Julie --

All pet products require the submission of companion animal safety studies prior to registration. In addition, they are still obligated to report under 6a2. The language below is referring to enhance reporting for spot-ons, which as of now is only required for spot-on products. My feeling was

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Breeden-Alemi, Julie
Sent: Wednesday, August 03, 2016 7:22 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: RE: Agenda 8/3/16 - Pyrethroid Team Meeting

Just a question regarding excluding products other than spot-ons...

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Ex. 5 Deliberative Process (DP)

From: Davis, Kable
Sent: Wednesday, August 03, 2016 6:52 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: FW: Agenda 8/3/16 - Pyrethroid Team Meeting

Hi Marietta and Julie --

Should one of us attend this pyrethroid meeting today? Unfortunately, we are all invited to the Seresto pre-meeting. Their suggested language looks fine to me, however I don't think

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Ex. 5 Deliberative Process (DP)

Marietta -- you had suggested the text should explain the

Ex. 5 Deliberative Process (DP)

I'm guessing they

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thanks,
Bo

From: Waleko, Garland
Sent: Tuesday, August 02, 2016 5:24 PM
To: Anderson, Neil <Anderson.Neil@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Costello, Kevin <Costello.Kevin@epa.gov>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>; Livingston, Wilhelmena <Livingston.Wilhelmena@epa.gov>; Mannix, Marianne <Mannix.Marianne@epa.gov>; Perry, Tracy <Perry.Tracy@epa.gov>; Pruitt, Brittany <Pruitt.Brittany@epa.gov>; Zavala, Miguel A. <Zavala.Miguel@epa.gov>; Judkins, Donna <Judkins.Donna@epa.gov>; Kiernan, Brian <Kiernan.Brian@epa.gov>; Melendez, Jose <Melendez.Jose@epa.gov>; Sappington, Keith <Sappington.Keith@epa.gov>; Shamim, Mah <Shamim.Mah@epa.gov>; Vaughan, Allen <Vaughan.Allen@epa.gov>; Went, Stephen <Went.Stephen@epa.gov>; White, Katrina <White.Katrina@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>;

Cook, Colwell <cook.colwell@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>; Doucoure, Cynthia <Doucoure.Cynthia@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Jarboe, Stephen <Jarboe.Steve@epa.gov>; Jones, Arnet <Jones.Arnet@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Mallampalli, Nikhil <Mallampalli.Nikhil@epa.gov>; May, Brenda <May.Brenda@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Myers, Clayton <Myers.Clayton@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Rowland, Jess <Rowland.Jess@epa.gov>; Sims, Diann <Sims.Diann@epa.gov>; Swartz, Christina <Swartz.Christina@epa.gov>; Wyatt, TJ <Wyatt.TJ@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Anderson, Brian <Anderson.Brian@epa.gov>; Eckel, William <Eckel.William@epa.gov>; Wait, Monica <Wait.Monica@epa.gov>; Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Louie-Juzwiak, Rosanna <Louie-Juzwiak.Rosanna@epa.gov>; Basu, Bilin <Basu.Bilin@epa.gov>; Kettl, Brian <Kettl.Brian@epa.gov>; Sell, Nathan <Sell.Nathan@epa.gov>; Adler, Bonnie <Adler.Bonnie@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Breithaupt, James <Breithaupt.James@epa.gov>; Parsons, Laura <Parsons.Laura@epa.gov>; Williams, Sanyvette <Williams.Sanyvette@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>; King, Marquee <King.Marquee@epa.gov>; Arrington, Linda <Arrington.Linda@epa.gov>; Parker, James <Parker.James@epa.gov>; Ricciardi, Rachel <Ricciardi.Rachel@epa.gov>; Chao, Julie <Chao.Julie@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Jones, RDavid <Jones.Rdavid@epa.gov>; Page, Jordan <Page.Jordan@epa.gov>; Bartow, Susan <Bartow.Susan@epa.gov>; Fry, Meridith <Fry.Meridith@epa.gov>; Housenger, Justin <Housenger.Justin@epa.gov>; Spatz, Dana <Spatz.Dana@epa.gov>; Piansay, Maria <Piansay.Maria@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Hawkins, Caleb <Hawkins.Caleb@epa.gov>; English, LisaRenee <English.LisaRenee@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>

Subject: Agenda 8/3/16 - Pyrethroid Team Meeting

Agenda – Interdivisional Pyrethroid Team Meeting 8/3/16, 3:00-3:30 pm

HED

- Any updates or issues? The most recent schedule is attached.

RD

- Pet incident data - from our last discussion there were a few different suggestions on how to address pet incidents with pyrethroids. Please look over the text below to see if this level of information would be adequate or if we want to say anything else at this time.

Draft Pet Incident Summary - There are a number of pyrethroids with registered use as direct treatment on pets. Some of the most popular pet products are spot-on products. EPA has been engaged with stakeholders on a variety of different actions to address risks to pets from the use of pet spot-on products; additional information on this project can be found here: <https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects>. As additional information is gathered through this project EPA will be evaluating the use of pet spot-on products, including those that contain pyrethroids, to determine if additional changes are needed to those registrations. (Do we want to say anything about future plans to

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EFED/PRD

- **Agricultural and mosquito section** – in review in PRD
- **Rationale document** – draft with Mah for PRT review as far as general direction and conclusions. Draft is also with PRD management. PRD doesn't expect comments at this point, and will have an updated draft in the middle of August for more detailed review
- **Bee section?**
- Stakeholder meetings - PWG August meeting, PWG October benefits meeting, California wastewater/stormwater folks

BEAD

- Characterization for Agricultural section – holding off to finalize
- Mosquito section progress/issues?

Garland Waleko
Chemical Review Manager (RMIB2)
Pesticide Re-evaluation Division (PRD)
Office of Pesticide Programs (OPP)
U.S. Environmental Protection Agency
(703) 308-8049
waleko.garland@epa.gov

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/10/2016 4:44:32 PM
To: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]
CC: Evans, Elizabeth [Evans.Elizabeth@epa.gov]
Subject: RE: Conference Call with PMRA; Seresto

Sorry — I just received your email. I'll make sure we ask the questions outlined in your email.

From: Rossmeisl, Colleen
Sent: Wednesday, August 10, 2016 10:15 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Adler, Bonnie <Adler.Bonnie@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>
Cc: Evans, Elizabeth <Evans.Elizabeth@epa.gov>
Subject: RE: Conference Call with PMRA; Seresto

Hi all -

I will likely be able to call in today for the meeting, but I am on leave with a couple of kids in the house, so not sure how much talking I will do!

My main questions for PMRA are re:

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Thanks!
Colleen

-----Original Appointment-----

From: Davis, Kable
Sent: Saturday, August 06, 2016 1:08 AM
To: Davis, Kable; Rossmeisl, Colleen; Echeverria, Marietta; Breeden-Alemi, Julie; Miller, David; Recore, Shanna; Adler, Bonnie; Biscoe, Melanie
Cc: Evans, Elizabeth
Subject: Conference Call with PMRA; Seresto
When: Wednesday, August 10, 2016 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS7671C/Potomac-Yard-One

Exchange Server re-created a meeting that was missing from your calendar.

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/11/2016 8:15:39 PM
To: Doug Spilker [doug.spilker@bayer.com]
CC: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Seresto meeting - we plan to use a projector

Hi Doug --

Thanks for the email and I hope all is well. No worries -- I was able to switch us to a conference room that has a projector.

Thanks for checking.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Thursday, August 11, 2016 2:46 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Seresto meeting - we plan to use a projector

Hi Bo,
I called and your phone message said you were out -- hopefully taking some vacation. I thought I would send an email too.

For our Seresto meeting on Wednesday, August 17th, we have changed our mind and plan to project our presentation. We will bring our own computer etc. I hope this does not cause any problem.

Best Regards,

Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs

Bayer Animal Health
Bayer HealthCare LLC
P.O. Box 390
Shawnee Mission, KS 66201-0390
USA

Office: +1 -913-268-2751
Mobile: +1 -816-506-3102
Email: doug.spilker@bayer.com

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Message

From: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
Sent: 8/16/2016 11:38:02 AM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]
Subject: Seresto dermal studies

Hi all -

Sorry I won't be at the meeting today but I think you have my thoughts based on the analysis I did and meetings we have had.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thanks!
Colleen

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/18/2016 6:18:50 PM
To: Doug Spilker [doug.spilker@bayer.com]
CC: Bruce Martin [bruce.martin@bayer.com]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Seresto Meeting of August 17, 2016 - Copy of Presentation (CBI)

Received. Thanks, Doug. I'll be sure to treat the slides as CBI.

Thanks again for sending.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Thursday, August 18, 2016 2:17 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Bruce Martin <bruce.martin@bayer.com>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Seresto Meeting of August 17, 2016 - Copy of Presentation (CBI)

Dear Mr. Davis,

As requested, please find attached a copy of our presentation from the Seresto Meeting with the Agency on August 17, 2016. This entire document contains Confidential Business Information, is marked as such, and should be handled appropriately as CBI within the Agency.

Please ensure that this document is provided as soon as possible to all EPA attendees to the meeting, and any other staff that would benefit from the information.

Best Regards,

Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs

Bayer Animal Health
Bayer HealthCare LLC
P.O. Box 390
Shawnee Mission, KS 66201-0390
USA

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Email: doug.spilker@bayer.com

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Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/31/2016 2:27:06 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: FW: Seresto Documents

FYI

From: Overstreet, Anne
Sent: Wednesday, August 31, 2016 10:26 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Subject: RE: Seresto Documents

Hi Bo, yes, I passed along the information – thank you! Also, they noted that folks have not collected any additional incident information related to the collars but Patti (our regional contact) would ask again.

From: Davis, Kable
Sent: Wednesday, August 31, 2016 10:25 AM
To: Overstreet, Anne <overstreet.anne@epa.gov>
Subject: RE: Seresto Documents

Hi Anne –

I didn't receive a response to my email below and I wanted to double check and confirm that you received it.

Thanks much,
Bo

From: Davis, Kable
Sent: Tuesday, August 30, 2016 8:36 AM
To: Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Seresto Documents

Hi Anne –

Here are the reviews used to originally register Seresto. I've included the following:

1. HED Risk Assessment
2. Acute Toxicity Review
3. Companion Animal Review
4. Rate of Release Document

Question – do you happen know if the tribes have been reporting these Seresto incidents? Also, do you have any idea on the number and severity?

Hope this helps.
Bo

Kable Bo Davis
Product Manager 3

Invertebrate & Vertebrate Branch 1

(703) 306-0415

davis.kable@epa.gov

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 9/6/2016 6:15:14 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: Automatic reply: Seresto collar summary

I'm currently out of the office and will be returning Thursday, September 8, 2016. While I'm away, you may contact Jenn Saunders at 347-0156.

Thanks,
Bo

Message

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 9/6/2016 6:15:14 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: Automatic reply: Seresto collar summary

I will be out of the office on leave from Friday 2 September through Wednesday 14 September,. I should have be accessing email on at least an occassional basis during this time.

If you need assistance during this time, please contact Matthew Crowley who will be acting branch chief for CEB/TEB at crowley.matthew@epa.gov.

Message

From: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
Sent: 9/6/2016 7:58:58 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Seresto collar summary

Will do - will let you know what I think.

Thanks!

Colleen

From: Echeverria, Marietta
Sent: Tuesday, September 06, 2016 3:10 PM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Cc: Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: Re: Seresto collar summary

Yes, please read the bayer document before finalizing your review. Late this week or early next week is fine.
Thanks

Sent from my iPhone

On Sep 6, 2016, at 3:06 PM, Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov> wrote:

Sorry I haven't gotten back to you yet - the reference I need is the text highlighted in yellow in the document that David circulated previously. Refers to sales data from Bayer. Do you have the document?

I started to look through Bayer's document but haven't finished.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

I am not sure the exact

timeline for sending our letter, but it may be useful for me to at least read through that document before sending our memo. When do you want to send the analysis to Bayer? I thought probably this week?

Thanks -
Colleen

From: Evans, Elizabeth
Sent: Tuesday, September 06, 2016 3:01 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: Re: Seresto collar summary

I don't think HED has objections to Colleen authoring the memo with no HED signature. I sent Colleen a note earlier- I can help her locate the reference related to sales data, but I am not sure exactly what she is looking for. Shanna is back tomorrow.

Thanks,

Liz

From: Echeverria, Marietta
Sent: Tuesday, September 6, 2016 2:15:12 PM
To: Rossmeisl, Colleen; Miller, David
Cc: Crowley, Matthew; Nguyen, James; Evans, Elizabeth; Recore, Shanna; Davis, Kable
Subject: Re: Seresto collar summary

All, I am fine with Colleen logging the document out through her branch and referencing the HED piece, if getting the dual signature is too difficult. Any thoughts on Bayer's latest submission?

From: Rossmeisl, Colleen
Sent: Friday, September 2, 2016 9:13:50 AM
To: Miller, David
Cc: Crowley, Matthew; Nguyen, James; Evans, Elizabeth; Recore, Shanna; Echeverria, Marietta; Davis, Kable
Subject: RE: Seresto collar summary

Hi David -

Thanks for the reply. Based on conversations with Bo yesterday, I think the idea was the memo would be from you, me and James. But if RD is OK with it, I think the memo could be from me and I could just reference that the appendix was provided by HED and your group. I cc'd Bo and Marietta here for their thoughts.

I can follow up with the other folks you mentioned to get the reference that we still need.

I hope you enjoy your trip!
Colleen

From: Miller, David
Sent: Thursday, September 01, 2016 3:47 PM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>
Subject: Re: Seresto collar summary

I've left and am in the Dulles waiting area right now. James or Liz or Shanna should get the reference you need.

You suggested that it was tough getting what James wrote into your document since it is so different. I agree with your suggestion about putting it into an Appendix.

Matt Crowley is acting and can sign the memo. But it's from you, right? Do you need a separate one from us? I thought you could just incorporate James's IRR etc. info into what you wrote.

I should have access to email, so can follow this as it moves along.

david.

From: Rossmeisl, Colleen
Sent: Thursday, September 1, 2016 2:31 PM
To: Miller, David
Subject: Seresto collar summary

Hi David -

Just wondering if you are still around or you are already gone. RD wants to get the signed memo for the Seresto review. I know we still need once reference for the sales data for the piece you sent me to be filled in. If we can't get it all tied up before you go, is someone able to sign the memo for you? Who should it be from - you and James? Anyone else?

Thanks for your help!
Colleen

Message

From: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
Sent: 9/7/2016 3:01:14 PM
To: Nguyen, James [Nguyen.James@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]
CC: Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]
Subject: RE: Seresto summary documents

Thanks James! I will use this version in the memo.
Colleen

From: Nguyen, James
Sent: Wednesday, September 07, 2016 10:19 AM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Sarkar, Bayazid <Sarkar.Bayazid@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>
Subject: RE: Seresto summary documents

Hi all,

I updated the reference of sale data in the file "Statistical Report of Seresto Incidence 2014-2015_DMiller comments_cmr_password_jn.docx". I did not have the data, and I forgot that Bayer did NOT electronically send us the sale data. So, there was no file name for the sale data.

Thanks
James

From: Rossmeisl, Colleen
Sent: Thursday, September 01, 2016 12:38 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>
Subject: RE: Seresto summary documents

It was recommended I go ahead and share this with Marietta and Bo at this point in time, since David will be out soon. Any feedback or comments appreciated.

Thanks!
Colleen

From: Rossmeisl, Colleen
Sent: Thursday, September 01, 2016 8:24 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: Seresto summary documents

Hi all -

I incorporated the analysis David and James did into the document I wrote. Email is encrypted and documents password protected with same one Bo sent previously. I did make some editorial (primarily) changes to the HED statistics write-up and then included it as an Attachment to what I did, as it seemed to fit that way, but I am open to any other suggestions on how to combine the documents. I also included the original statistical analysis in track changes but then copied the clean version into the combined document. Feel free to remove any edits I made - was just trying to help the flow a little. (And is it Bayer's products or Bayer products? I changed it but we can always revert it back with find and replace).

Just as an FYI, I also attached my comments on Bayer's review of the PMRA analysis thus far. I think they are

Ex. 5 Deliberative Process (DP)

Also, just wanted to make you aware - we had our incident SWAT team meeting the other day, where we are working on a protocol to become aware of high priority incidents sooner and bring them to the appropriate folk's attention. There were 7 human incidents reported associated with the Seresto pet collar in the first two weeks of August - I am not sure if that is high, but it was more than any other product we looked at in the two week period.

Let me know what you think of the summary review and if we want to share with Marietta and Bo sooner rather than later to get comments as David is out after today. I am not sure exactly what format they would like this is in.

Thanks!
Colleen

Message

From: Evans, Elizabeth [Evans.Elizabeth@epa.gov]
Sent: 9/7/2016 1:26:49 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]
CC: Crowley, Matthew [Crowley.Matthew@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]
Subject: RE: Seresto collar summary

Please resend the Bayer submission. If it is from Bo on 8/18 I cannot open the email.

From: Echeverria, Marietta
Sent: Tuesday, September 06, 2016 2:15 PM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: Re: Seresto collar summary

All, I am fine with Colleen logging the document out through her branch and referencing the HED piece, if getting the dual signature is too difficult. Any thoughts on Bayer's latest submission?

From: Rossmeisl, Colleen
Sent: Friday, September 2, 2016 9:13:50 AM
To: Miller, David
Cc: Crowley, Matthew; Nguyen, James; Evans, Elizabeth; Recore, Shanna; Echeverria, Marietta; Davis, Kable
Subject: RE: Seresto collar summary

Hi David -

Thanks for the reply. Based on conversations with Bo yesterday, I think the idea was the memo would be from you, me and James. But if RD is OK with it, I think the memo could be from me and I could just reference that the appendix was provided by HED and your group. I cc'd Bo and Marietta here for their thoughts.

I can follow up with the other folks you mentioned to get the reference that we still need.

I hope you enjoy your trip!
Colleen

From: Miller, David
Sent: Thursday, September 01, 2016 3:47 PM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>
Subject: Re: Seresto collar summary

I've left and am in the Dulles waiting area right now. James or Liz or Shanna should get the reference you need.

You suggested that it was tough getting what James wrote into your document since it is so different. I agree with your suggestion about putting it into an Appendix.

Matt Crowley is acting and can sign the memo. But it's from you, right? Do you need a separate one from us? I thought you could just incorporate James's IRR etc. info into what you wrote.

I should have access to email, so can follow this as it moves along.

david.

From: Rossmeisl, Colleen

Sent: Thursday, September 1, 2016 2:31 PM

To: Miller, David

Subject: Seresto collar summary

Hi David -

Just wondering if you are still around or you are already gone. RD wants to get the signed memo for the Seresto review. I know we still need once reference for the sales data for the piece you sent me to be filled in. If we can't get it all tied up before you go, is someone able to sign the memo for you? Who should it be from - you and James? Anyone else?

Thanks for your help!
Colleen

Message

From: Nguyen, James [Nguyen.James@epa.gov]
Sent: 9/7/2016 2:18:50 PM
To: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]
CC: Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]
Subject: RE: Seresto summary documents
Attachments: Seresto summary review 9_1_16_combined_password.docx; Human Case Assessment Critique 2016_08_19_BAYER CBI_cmr comments_passwor....pdf; Statistical Report of Seresto Incidence 2014-2015_DMILLER comments_cmr_password_jn.docx

Hi all,

I updated the reference of sale data in the file "Statistical Report of Seresto Incidence 2014-2015_DMILLER comments_cmr_password_jn.docx". I did not have the data, and I forgot that Bayer did NOT electronically send us the sale data. So, there was no file name for the sale data.

Thanks
James

From: Rossmeisl, Colleen
Sent: Thursday, September 01, 2016 12:38 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>
Subject: RE: Seresto summary documents

It was recommended I go ahead and share this with Marietta and Bo at this point in time, since David will be out soon. Any feedback or comments appreciated.

Thanks!
Colleen

From: Rossmeisl, Colleen
Sent: Thursday, September 01, 2016 8:24 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: Seresto summary documents

Hi all -

I incorporated the analysis David and James did into the document I wrote. Email is encrypted and documents password protected with same one Bo sent previously. I did make some editorial (primarily) changes to the HED statistics write-up and then included it as an Attachment to what I did, as it seemed to fit that way, but I am open to any other suggestions on how to combine the documents. I also included the original statistical analysis in track changes but then copied the clean version into the combined document. Feel free to remove any edits I made - was just trying to help the flow a little. (And is it Bayer's products or Bayer products? I changed it but we can always revert it back with find and replace).

Just as an FYI, I also attached my comments on Bayer's review of the PMRA analysis thus far. I think they are

Ex. 5 Deliberative Process (DP)

Also, just wanted to make you aware - we had our incident SWAT team meeting the other day, where we are working on a protocol to become aware of high priority incidents sooner and bring them to the appropriate folk's attention. There were 7 human incidents reported associated with the Seresto pet collar in the first two weeks of August - I am not sure if that is high, but it was more than any other product we looked at in the two week period.

Let me know what you think of the summary review and if we want to share with Marietta and Bo sooner rather than later to get comments as David is out after today. I am not sure exactly what format they would like this is in.

Thanks!
Colleen

Appointment

From: DCRoomPYS7621B/Potomac-Yard-One [DCRoomPYS7621B@epa.gov]
Sent: 9/8/2016 1:42:39 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]

Subject: Accepted: seresto
Location: DCRoomPYS7621B/Potomac-Yard-One

Start: 9/8/2016 8:00:00 PM
End: 9/8/2016 8:30:00 PM

Recurrence: (none)

Your request was accepted.

Sent by Microsoft Exchange Server 2016

Message

From: Evans, Elizabeth [Evans.Elizabeth@epa.gov]
Sent: 9/7/2016 12:48:11 PM
To: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]
CC: Crowley, Matthew [Crowley.Matthew@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]
Subject: RE: Seresto collar summary
Attachments: seresto sales volume and incident rate analysis rev3.pdf

Let me know if this is what you are looking for. Please note this may contain proprietary or confidential information.

From: Rossmeisl, Colleen
Sent: Tuesday, September 06, 2016 3:07 PM
To: Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: RE: Seresto collar summary

Sorry I haven't gotten back to you yet - the reference I need is the text highlighted in yellow in the document that David circulated previously. Refers to sales data from Bayer. Do you have the document?

I started to look through Bayer's document but haven't finished. Ex. 5 Deliberative Process (DP)
Ex. 5 Deliberative Process (DP) I am not sure the exact timeline for sending our letter, but it may be useful for me to at least read through that document before sending our memo. When do you want to send the analysis to Bayer? I thought probably this week?

Thanks -
Colleen

From: Evans, Elizabeth
Sent: Tuesday, September 06, 2016 3:01 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: Re: Seresto collar summary

I don't think HED has objections to Colleen authoring the memo with no HED signature. I sent Colleen a note earlier- I can help her locate the reference related to sales data, but I am not sure exactly what she is looking for. Shanna is back tomorrow.

Thanks,

Liz

From: Echeverria, Marietta
Sent: Tuesday, September 6, 2016 2:15:12 PM
To: Rossmeisl, Colleen; Miller, David

Cc: Crowley, Matthew; Nguyen, James; Evans, Elizabeth; Recore, Shanna; Davis, Kable

Subject: Re: Seresto collar summary

All, I am fine with Colleen logging the document out through her branch and referencing the HED piece, if getting the dual signature is too difficult. Any thoughts on Bayer's latest submission?

From: Rossmeisl, Colleen

Sent: Friday, September 2, 2016 9:13:50 AM

To: Miller, David

Cc: Crowley, Matthew; Nguyen, James; Evans, Elizabeth; Recore, Shanna; Echeverria, Marietta; Davis, Kable

Subject: RE: Seresto collar summary

Hi David -

Thanks for the reply. Based on conversations with Bo yesterday, I think the idea was the memo would be from you, me and James. But if RD is OK with it, I think the memo could be from me and I could just reference that the appendix was provided by HED and your group. I cc'd Bo and Marietta here for their thoughts.

I can follow up with the other folks you mentioned to get the reference that we still need.

I hope you enjoy your trip!

Colleen

From: Miller, David

Sent: Thursday, September 01, 2016 3:47 PM

To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>

Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>

Subject: Re: Seresto collar summary

I've left and am in the Dulles waiting area right now. James or Liz or Shanna should get the reference you need.

You suggested that it was tough getting what James wrote into your document since it is so different. I agree with your suggestion about putting it into an Appendix.

Matt Crowley is acting and can sign the memo. But it's from you, right? Do you need a separate one from us? I thought you could just incorporate James's IRR etc. info into what you wrote.

I should have access to email, so can follow this as it moves along.

david.

From: Rossmeisl, Colleen

Sent: Thursday, September 1, 2016 2:31 PM

To: Miller, David

Subject: Seresto collar summary

Hi David -

Just wondering if you are still around or you are already gone. RD wants to get the signed memo for the Seresto review. I know we still need once reference for the sales data for the piece you sent me to be filled in. If we can't get it all tied up before you go, is someone able to sign the memo for you? Who should it be from - you and James? Anyone else?

Thanks for your help!
Colleen

Message

From: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
Sent: 9/12/2016 5:33:18 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Bayer review of PMRA Seresto collar review

Thanks Marietta - I will wait to hear back from you.

From: Echeverria, Marietta
Sent: Monday, September 12, 2016 12:41 PM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Cc: Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Spatz, Dana <Spatz.Dana@epa.gov>
Subject: RE: Bayer review of PMRA Seresto collar review

Hi Colleen,

Thanks for reading through the Bayer submission. Interestingly, we got a note from Bayer last week requesting a meeting with the PRD and HED directors and they're legal counsel this week. We have a pre-meeting with the DDs at 2:30 today. My inclination is to finalize the memo as is so we can start the negotiations. But let me confirm and get back to you this afternoon. Thanks again for your work on this project.

Marietta

From: Rossmeisl, Colleen
Sent: Monday, September 12, 2016 11:43 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Spatz, Dana <Spatz.Dana@epa.gov>
Subject: Bayer review of PMRA Seresto collar review

Hi Marietta -

I finished reading through and doing some analysis of the Bayer report on the pet incident data. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) It might be good for the group to meet to discuss the points that Bayer has raised and I can share my opinion on those and see what the group thinks overall.

Do you have any thoughts on what we want to do with this in regards to the memo we have already prepared? I am not sure if you want to incorporate this review into that, as that would require more time. I do not see anything in the Bayer report that would significantly alter what is in the memo now.

Let me know how you want to proceed.

Thanks!

Colleen

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 9/13/2016 11:46:12 AM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: 1-pager Question

Hi Marietta –

During the pre-meeting yesterday, I felt like we discussed 2 different versions of the Seresto 1-pager. At one point we

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

It was my understanding that I was going to write up the second 1-pager and have Colleen and David look over it. I'm assuming we will hold off writing the first version until after we have run the idea past Michele and she agrees. Was that your understanding as well?

FYI – I'm supposed to call Michele at 8:30 am.

Thanks,
Bo

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 9/12/2016 8:53:58 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
CC: Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Spatz, Dana [Spatz.Dana@epa.gov]
Subject: RE: Bayer review of PMRA Seresto collar review

Hi Colleen –

Please hold off finalizing your review. Bayer has requested a meeting with the Agency and I believe PRD plans on scheduling it for late next week. Prior to that meeting, we plan on briefing Jack on the status of review and our proposal

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

I plan on writing a short 1-pager for the briefing and will forward to you and David's team for review. Thanks for holding off finalizing your review.

Please feel free to call me tomorrow, if you want to discuss further.

Thanks,
Bo

From: Echeverria, Marietta
Sent: Monday, September 12, 2016 12:41 PM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Cc: Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Spatz, Dana <Spatz.Dana@epa.gov>
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To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>; Spatz, Dana <Spatz.Dana@epa.gov>
Subject: Bayer review of PMRA Seresto collar review

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Let me know how you want to proceed.

Thanks!

Colleen

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 9/15/2016 8:36:33 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: FW: PNR1427 Insecticide (Seresto Collar) - 11556-155
Attachments: PNR 1427 Insecticide Withdrawal Letter.pdf

FYI – Bayer withdrew their Seresto amendment adding medium sized dogs.

From: Todd Frank [mailto:todd.frank@bayer.com]
Sent: Thursday, September 15, 2016 4:30 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Subject: PNR1427 Insecticide (Seresto Collar) - 11556-155

Hello Bo,

Please see attached letter.

I submitted the letter to your attention today via Federal Express. It will arrive tomorrow to the mail room.

Do you need anything else from us?

Todd

Best regards,

Todd Frank
Regulatory Affairs Consultant

Bayer: Science For A Better Life

Bayer Animal Health
P.O. 390
Shawnee Mission, KS 66201
USA
Tel: +1 913 268 2585
E-mail: todd.frank@bayer.com
Web: <http://www.bayer.com>

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Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 2/9/2016 4:51:48 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Question on Veterinary PV-Works/PV-Analyzer compatibilities with respect to export to MS Excel template

Hi David –

I appreciate the update. I don't feel like I need to be on the call, however I would love to hear how it goes.

Enjoy your day.

Bo

From: Miller, David
Sent: Tuesday, February 09, 2016 11:49 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: FW: Question on Veterinary PV-Works/PV-Analyzer compatibilities with respect to export to MS Excel template

A quick update on the status of our external communications with respect to Seresto:

1. You should have received an email I sent yesterday from the European Medicines Agency on Seresto. They said: talk to the Germans. So, I sent an email to them yesterday asking the same question.
2. See below for the response from a company that makes commercial pharmacovigilance software. I understand Bayer Animal Health – and maybe Safety Call, Inc. – use this. While we will stick with our spreadsheet format for getting in the spot on data (we can't require them to buy and use commercial software), we thought it was important that Spot-on registrants who do use some commercially available software be able to export their data to an Excel format along the lines of our template. So.... we will be asking the PV-Works people this in a future call with them. Recall Bayer said that they had problems getting their Seresto data (from what I believe was in PV-Works) into our spreadsheet.
3. James is finishing up the spreadsheet template for the spot-on products for external (e.g, FDA) review.
4. We understand that you would likely like to get a note out to registrants during March to let them know that – for most of them – quarterly reporting is no longer required. March is good so as to avoid them starting reporting on this for the January through March 2016 quarter. However, we may want them to try out the template for January through March so as we can offer feedback. And then have them continue with it for the March through December time frame.

Do you two want to be involved in the call with the PV-Works folks (now apparently part of Ennov) ?

David

From: Nic Pillinger [<mailto:nic.pillinger@ennov.com>]
Sent: Tuesday, February 09, 2016 11:30 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: FW: Question on Veterinary PV-Works/PV-Analyzer compatibilities with respect to export to MS Excel template

Hi David

I'd be very happy to talk to you about all of your requirements for handling PV data. As you know we are already working with FDA CVM and USDA CVB in this area. When is a good time for a call and / or demo of the solutions?

Regards
Nic

P.S. As you'll see from my sign-off below, Assured Information System the original developers of the PV-Works and PV-Analyser software, are now part of Ennov – a supplier of various other software solutions to the life sciences sector. That said, the PV operation continues with the legal company name of Assured, although we often market ourselves as Ennov PV. I have personally been working with the PV division for 13 years and have a lot of direct experience in working with these previous Regulatory projects.

Nic Pillinger
Director of Pharmacovigilance Products



Email nic.pillinger@ennov.com
Office +44 (0)1480 212223
Visit us <http://www.ennov.com>

From: Miller, David [<mailto:Miller.DavidJ@epa.gov>]
Sent: 08 February 2016 23:13
To: info@assuredpv.com
Subject: Question on Veterinary PV-Works/PV-Analyzer compatibilities with respect to export to MS Excel template

We are currently considering ways/formats that we might like some veterinary pharmacovigilance data to be submitted to us, and would ideally like it to be in a way that would generally be compatible with available commercial software like PV-Works. Please call me about the ability of the PV-Works and/or PV-Analyzer software to export into a pre-formatted MS Excel worksheet template that we are developing.

Please call me at the number below at your convenience.

Tx.

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicovigilance & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 9/28/2016 4:17:47 PM
To: Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]
CC: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Seresto - Quick Clarification on Margin of Safety
Attachments: Companion Animal Review.pdf

Here you go.

From: Biscoe, Melanie
Sent: Wednesday, September 28, 2016 12:10 PM
To: Davis, Kable <Davis.Kable@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: RE: Seresto - Quick Clarification on Margin of Safety

Yes, that makes total sense!

If you have the companion animal review handy, I would like to have it handy. I have never looked at a review of that type of study.

Melanie Biscoe

Team Leader, Risk Management and Implementation Branch V
Pesticide Re-evaluation Division
Office of Pesticide Programs, US EPA
biscoe.melanie@epa.gov
703-305-7106

From: Davis, Kable
Sent: Wednesday, September 28, 2016 12:09 PM
To: Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: RE: Seresto - Quick Clarification on Margin of Safety

Hi Melanie –

I believe it means the animals were exposed to either 3 or 4 times the labeled dose and didn't show unacceptable levels of adverse effects. Does this answer your question? I can send the companion animal review if that would be helpful.

Thanks,
Bo

From: Biscoe, Melanie
Sent: Wednesday, September 28, 2016 11:14 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Seresto - Quick Clarification on Margin of Safety
Importance: High

Bo and Julie,

Yu-Ting had a comment on your language regarding the margin of safety for companion animals. Basically she was asking what this sentence means:

Ex. 5 Deliberative Process (DP)

I'm not sure what the margin of safety is in relation to a companion animal study, so can't really describe this further. Would like to know more (and be able to put a sentence with some context in).

Yu-Ting's only other substantive comment

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Melanie Biscoe

Team Leader, Risk Management and Implementation Branch V
Pesticide Re-evaluation Division
Office of Pesticide Programs, US EPA
biscoe.melanie@epa.gov
703-305-7106

Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 3/17/2016 1:32:01 PM
To: Miller, David [Miller.DavidJ@epa.gov]
CC: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities
Attachments: 20 85 Request Template EPA Draft.doc

Importance: High

David —

Please see the email below from OGC. We'll let you know more when we can.

From: Knorr, Michele
Sent: Thursday, March 17, 2016 9:25 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities
Importance: High

Don — here is the letter developed for EPA's visit to FDA. Thanks for looking at this when you return to the office.

Bo/Julie — Don has reviewed agreements like this in the past. He will be out after today until a week from Monday. He said he could look at it at that time. I believe the visit isn't until April, so I hope that timing works for you.

Michele L. Knorr
Attorney
Pesticides and Toxics Law Office
Office of General Counsel
202-564-5631

From: Davis, Kable
Sent: Tuesday, March 15, 2016 1:55 PM
To: Knorr, Michele <knorr.michele@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi Michele —

Please see the chain of emails below. I forwarded this to Susan and she wanted me to double check with you on whether or not it's appropriate for her to sign it.

Thanks,
Bo

From: Davis, Kable
Sent: Tuesday, March 15, 2016 9:30 AM
To: Lewis, Susan <Lewis.Susan@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi Susan –

HED and RD has an upcoming meeting with FDA to discuss enhanced reporting for spot-on products and FDA wants us to sign the attached letter. David Miller assumes they need this document so they feel comfortable showing us what they have in terms of incidents for pet products. He also suggested you be the person that signs the letter. Are you comfortable with this? If so, I'll put everything into our letterhead and forward to you for signature.

Thanks much,
Bo

From: Miller, David
Sent: Tuesday, March 15, 2016 9:04 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>
Subject: FW: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

FYI – apparently, they want us to fill this out saying that we want access to

- The CVM Adverse Drug Event database, called “PV Works / PV Analyser”, which includes the numerous data elements defined in Form FDA 1932, and which may include Personal Privacy Information and Confidential Commercial Information

pursuant to 21 C.F.R. § 20.85:

and that this has PPI and Confidential Commercial Information. Not sure that we want this –and we certainly would not be taking this data away or have it here at EPA. My conversation with FDA's John Baker was just for us to bring some summary information and also discuss an as-of-yet blank template we are producing. We would also discuss our plans for the spot on analysis (along the lines of what we did for Seresto) But it may be FDA wants to show us (presumably on screen) what they have and to feel comfortable with us seeing it, they need to have this form.

So.. just FYI. Do you know what we need to do to get this done here. Would it be appropriate for Susan Lewis be Agency rep to sign on the “Agency Representative Signature Line”

Bottom line: we will not be taking any FDA incident data away with us from FDA. Frankly, we hardly have time enough to deal with our own EPA spot on data, never mind dealing with FDA's as well !!

David.

From: Garcia-Malene, Gorka [<mailto:Gorka.Garcia-Malene@fda.hhs.gov>]

Sent: Monday, March 14, 2016 2:49 PM

To: Miller, David <Miller.DavidJ@epa.gov>

Cc: Baker, John D <John.Baker@fda.hhs.gov>

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Good Afternoon David,

Attached please find a template for the 20.85 agreement for your upcoming visit to FDA. Please complete the document as appropriate, printing it out in your agency's letterhead, and return it to us for processing.

Let me know if there are any questions.

Gorka

From: Baker, John D

Sent: Thursday, March 10, 2016 4:09 PM

To: Miller, David

Cc: Garcia-Malene, Gorka; Baker, John D

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi David,

To facilitate discussion of any MOU issues, I copied my CVM colleague, Gorka Garcia-Malene for his insight.

Also, have you determined if Monday, April 11th is a good day for your visit?

Best regards,
John

From: Miller, David [<mailto:Miller.DavidJ@epa.gov>]

Sent: Wednesday, March 09, 2016 8:01 AM

To: Baker, John D

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Dear Dr. Baker,

When we last spoke, we discussed visiting you folks up in White Oak on either Tuesday 22 February or Tuesday 29 February. I said I'd get back to you after I checked re: people availability here, with you indicating you would block off portions of both days.

This email is to let you know that Tuesday 29 February is ok with us. I am thinking perhaps we could set aside perhaps a 1 ½ block of time inside a 10 am to noon window. Would that be ok with you? I am hoping that would avoid the traffic. We would likely send you up some material in advance of this (e.g., our draft Pet Spot-on data entry spreadsheet that we'd very much appreciate your thoughts on) so you would have a chance to review it ahead of time.

I think you were going to check the EPA-FDA MOU to ensure that FDA would be able to do this. You didn't think that there would be a problem. Did it turn out that way and thus we are all set in that regard?

Again, we look forward to meeting with you and your team.

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Miller, David
Sent: Friday, March 04, 2016 3:24 PM
To: 'John.Baker@fda.hhs.gov' <John.Baker@fda.hhs.gov>
Subject: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Dear Dr. Baker,

My name is David Miller and I am a branch chief in the US Environmental Protection Agency's Office of Pesticide Programs of a branch which deals with post-marketing surveillance and toxicovigilance issues associated with pet products. As you may know, the US EPA is responsible for regulating pet spot-on products, and we are currently re-looking at pet incidents associated with these products.

By way of background, we originally began looking at spot-on incidents several years ago, with information and background on this work available at: <http://www.epa.gov/pets> and <http://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects>. Note that this information is current as about 5 or 6 years ago, based on what we knew then and does not reflect current activities. One of the outcomes of this initial look of several years ago was to require the spot-on manufacturers (aka pesticide registrants) to submit to the Agency enhanced pet incident reports on a quarterly basis.

We now have about 5 years worth of enhanced reporting information and have developed thoughts on ways to go about analyzing and interpreting the data. Given the CVM's Division of Product Safety more extensive experience with this kind of information, we would like to meet with you to discuss where we are at and any suggestions you might have with respect to our activities in this area. To the extent that we at EPA follow similar practices to those of FDA/CVM (e.g, use of VedDRA terms, signal detection techniques and thresholds, etc.), this would probably be a good thing. To the extent we may differ, it would be good for us to be knowledgeable about why and where there are difference and be able to provide appropriate rationale. I note that we have conversed over the last several weeks with Rick Kingston of Safety Call and with Assure, the makers of PV-Works pharmacovigilance software (which we understand FDA's CVM makes extensive use of).

Is meeting with us something you would be willing and able to do sometime during the month of March? If you like, we would be willing to visit you to review where we are at and what we are thinking. We plan on meeting with the representatives from the Animal Health Institute (AHI) sometime after that as well as making available our data template and plans as part of a 90-day public comment period over the summer.

Thank you for any assistance you may be able to provide.

Regards,

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

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Message

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 3/17/2016 1:08:53 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
CC: Breeden, Julie [Breeden.Julie@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

OGC wants to look into this a little further. I'll let you know what they say.

From: Davis, Kable
Sent: Thursday, March 17, 2016 8:57 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

She wanted me to check with OGC. I'll send Michele an email asking for an update.

From: Miller, David
Sent: Thursday, March 17, 2016 8:55 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hello Bo,

Any word back from Susan? Although the meeting with FDA seems a ways off, there may be a lot of bureaucracy there so they probably want this document signed and returned soon.

David.

From: Davis, Kable
Sent: Tuesday, March 15, 2016 9:26 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Breeden, Julie <Breeden.Julie@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

Hi David --

I'll chat with Susan and will let you know what she says.

Stay tuned,
Bo

From: Miller, David

Sent: Tuesday, March 15, 2016 9:04 AM

To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>

Cc: Breeden, Julie <Breeden.Julie@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>

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Sent: Monday, March 14, 2016 2:49 PM

To: Miller, David <Miller.DavidJ@epa.gov>

Cc: Baker, John D <John.Baker@fda.hhs.gov>

Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

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Let me know if there are any questions.

Gorka

From: Baker, John D
Sent: Thursday, March 10, 2016 4:09 PM
To: Miller, David
Cc: Garcia-Malene, Gorka; Baker, John D
Subject: RE: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

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To: Baker, John D
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To: 'John.Baker@fda.hhs.gov' <John.Baker@fda.hhs.gov>
Subject: Pet Spot on Products and EPA request to meet with CVM Division of Product Safety on PV/surveillance activities

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Thank you for any assistance you may be able to provide.

Regards,

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 5/11/2016 3:01:30 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Knorr, Michele [Knorr.Michele@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]
Subject: Meeting with Bayer; Seresto
Location: DCRoomPYS7100/Potomac-Yard-One
Start: 6/9/2016 7:00:00 PM
End: 6/9/2016 8:00:00 PM
Show Time As: Busy

Required Attendees: Echeverria, Marietta; Miller, David; Knorr, Michele; Breeden, Julie; Biscoe, Melanie; Adler, Bonnie; Rossmeisl, Colleen; Recore, Shanna

This time-slot worked for the majority of people.

Bayer has requested a meeting to discuss the status of review for the submitted Seresto incidents. Below is their agenda (copied and pasted):

“Bayer HealthCare, Animal Health Division, is requesting a meeting with the Agency regarding the subject product.

The purpose of the meeting is for:

- 1. The Agency to provide us with an update regarding its current review of the incident data and other information we provided***
- 2. Bayer to provide a brief overview of our interpretation of the information***
- 3. The Agency to provide Bayer with an understanding of the Agency’s intentions and next steps***

Attending from Bayer HealthCare will be:

- Robert Zolynas, Head of Global Development***
- Bruce Martin, Director of Regulatory Affairs***
- Douglas Spilker, Manager of EPA Regulatory Affairs***
- Will Heeb, Manager of Pharmacovigilance***
- Jessica Monachello, Bayer General Legal Council***
- Roger Martella, Sidley Austin LLP”***

I’ll be sure to add any presentation or agenda items prior to the meeting. Let me know if I should invite others.

Michele – I sent you an invite, since it looks like they are bringing their legal counsel.

Call-in No:
Conf. Code

Ex. 6 PP - conference code/call in number

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/16/2016 8:32:20 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
Subject: Seresto Review
Location: DCRoomPYS7621B/Potomac-Yard-One
Start: 8/18/2016 8:00:00 PM
End: 8/18/2016 8:30:00 PM
Show Time As: Busy

Required Attendees: Miller, David; Echeverria, Marietta; Breeden-Alemi, Julie; Rossmeisl, Colleen

Let's meet and briefly discuss the timeline for HED completing their review for Seresto and what exactly the document will contain.

Appointment

From: Godfrey, Victoria (HC/SC) [victoria.godfrey@canada.ca]
Sent: 4/14/2016 1:57:13 PM
To: Godfrey, Victoria (HC/SC) [victoria.godfrey@canada.ca]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Breeden, Julie [Breedon.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Bruce, Dana (HC/SC) [dana.bruce@canada.ca]; Recore, Shanna [Recore.Shanna@epa.gov]
Subject: FW: Seresto update
Location: E564
Start: 4/19/2016 2:00:00 PM
End: 4/19/2016 2:30:00 PM
Show Time As: Busy

-----Original Appointment-----

From: Godfrey, Victoria (HC/SC) [mailto:victoria.godfrey@canada.ca]
Sent: Thursday, April 14, 2016 9:54 AM
To: Godfrey, Victoria (HC/SC); Bruce, Dana (HC/SC); Recore, Shanna
Subject: Seresto update
When: Tuesday, April 19, 2016 10:00 AM-10:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: E564

Hi there,

This meeting is scheduled to provide EPA with a verbal update of PMRA's Incident Reporting Program recommendation for Seresto Collars based on review of incidents. Our first senior management presentation is April 20th (we presented to our directorate – health – this week).

Teleconference:	Ex. 6 PP - conference code/call in number	Conference ID:	Ex. 6 PP - conference code/call in number	President Access	Ex. 6 PP - conference code/call in number
Local Dial-in Number:	Ex. 6 PP - conference code/call in number				

Thanks

Vicky

Appointment

From: Recore, Shanna [Recore.Shanna@epa.gov]
Sent: 5/3/2016 2:17:26 PM
To: Recore, Shanna [Recore.Shanna@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Breeden, Julie [Breeden.Julie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
CC: Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]
Subject: update regarding spot-ons and seresto
Location: DCRoomPYS10771/Potomac-Yard-One
Start: 5/5/2016 1:00:00 PM
End: 5/5/2016 2:00:00 PM
Show Time As: Busy

Required Attendees: Miller, David; Evans, Elizabeth; Davis, Kable; Echeverria, Marietta; Nguyen, James; Sarkar, Bayazid; Breeden, Julie;
Optional Attendees: Rossmeisl, Colleen
Arrington, Linda; Biscoe, Melanie; Adler, Bonnie

Let's meet for an update on where we are and next steps for spot-ons and Seresto.

Here is a look at the seasonal trend for Seresto with the new FY16 Q1 incidents



Appointment

From: Miller, David [Miller.DavidJ@epa.gov]
Sent: 5/24/2016 8:04:58 PM
To: Miller, David [Miller.DavidJ@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Sarkar, Bayazid [Sarkar.Bayazid@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Nguyen, James [Nguyen.James@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Britton, Wade [Britton.Wade@epa.gov]; VanAlstine, Julie [VanAlstine.Julie@epa.gov]; Hawkins, Monica [Hawkins.Monica@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
CC: Adler, Bonnie [Adler.Bonnie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]

Subject: Update -- and Discuss upcoming spot-on and Seresto activities and meetings

Attachments: Agenda and Notes from 5_13_16 Kingston meeting.docx

Location: DCRoomPYS10771/Potomac-Yard-One

Start: 5/25/2016 12:30:00 PM

End: 5/25/2016 1:30:00 PM

Show Time As: Busy

Required Attendees: Recore, Shanna; Sarkar, Bayazid; Evans, Elizabeth; Rossmeisl, Colleen; Breeden-Alemi, Julie; Echeverria, Marietta; Nguyen, James; Davis, Kable; Britton, Wade; VanAlstine, Julie; Hawkins, Monica; Davis, Donna
Optional Attendees: Adler, Bonnie; Biscoe, Melanie; Arrington, Linda

See agenda and notes from Rick Kingston meeting attached

David.

[Agenda and Notes from 5_13_16 Kingston meeting.docx](#)

P.S. I promise not to oversleep this meeting ; -)

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 5/27/2016 4:51:14 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]
Subject: Call with PMRA; Seresto
Location: DCRoomPYS7771D/Potomac-Yard-One
Start: 6/2/2016 5:00:00 PM
End: 6/2/2016 6:00:00 PM
Show Time As: Busy

Required Attendees: Echeverria, Marietta; Breeden-Alemi, Julie

Marietta – your counterpart at PMRA is Dana Bruce. They have agreed to chat with us regarding Seresto.

Call-in No: **Ex. 6 PP - conference code/call in number**
Conf. Code

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 6/2/2016 1:32:19 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lewis, Susan [Lewis.Susan@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]
CC: Bloom, Jill [Bloom.Jill@epa.gov]
Subject: Seresto Discussion
Location: DCRoomPYS7771D/Potomac-Yard-One
Start: 6/3/2016 5:30:00 PM
End: 6/3/2016 6:30:00 PM
Show Time As: Busy

Required Attendees: Guilaran, Yu-Ting; Lewis, Susan; Echeverria, Marietta; Breeden-Alemi, Julie; Arrington, Linda; Miller, David; Costello, Kevin; Biscoe, Melanie
Optional Attendees: Bloom, Jill

Let' meet and discuss the appropriate next steps for how to review the incidents for Seresto. Should the review be folded into reg review or should something be done more quickly?

Call-in No:

Ex. 6 PP - conference code/call in number

Conf. Code

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 5/25/2016 4:21:12 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Knorr, Michele [Knorr.Michele@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Adler, Bonnie [Adler.Bonnie@epa.gov]
Subject: Internal Seresto Meeting
Location: DCRoomPYS7671C/Potomac-Yard-One
Start: 6/7/2016 7:00:00 PM
End: 6/7/2016 8:00:00 PM
Show Time As: Busy

Required Attendees: Echeverria, Marietta; Miller, David; Knorr, Michele; Breeden-Alemi, Julie; Biscoe, Melanie; Adler, Bonnie

Michele –

We have a few questions for you concerning the upcoming meeting with Bayer (6/9/16) concerning Seresto. Below is the call-in information.

Call-in No: **Ex. 6 PP - conference code/call in number**
Conf. Code:

Message

From: Holmes, Jean [Holmes.Jean@epa.gov]
Sent: 3/20/2020 2:56:40 PM
To: Anderson, Brian [Anderson.Brian@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Matuszko, Jan [Matuszko.Jan@epa.gov]
Subject: RE: One more issue regarding pet incidents. Will discuss at EFED Management meeting Monday

Hi,

It is a general issue but I realized it when Mary was conducting the cholecalciferol risk assessment. Mary was told by **Ex. 5 Deliberative Process (DP)** I spoke to Melissa Panger and she indicated that the only

Ex. 5 Deliberative Process (DP)

Jean

From: Anderson, Brian <Anderson.Brian@epa.gov>
Sent: Thursday, March 19, 2020 1:29 PM
To: Holmes, Jean <Holmes.Jean@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Matuszko, Jan <Matuszko.Jan@epa.gov>
Subject: RE: One more issue regarding pet incidents. Will discuss at EFED Management meeting Monday

I saw that on your agenda – is that related to rodenticides?

From: Holmes, Jean <Holmes.Jean@epa.gov>
Sent: Thursday, March 19, 2020 1:27 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Matuszko, Jan <Matuszko.Jan@epa.gov>; Anderson, Brian <Anderson.Brian@epa.gov>
Subject: One more issue regarding pet incidents. Will discuss at EFED Management meeting Monday

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 7/30/2020 5:45:10 PM
To: Kraft, Erik [Kraft.Erik@epa.gov]; Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]; Shuler, Jamey [Shuler.Jamey@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: Fwd: Service Dog Killed by Seresto

FYI

Best,
Catherine
Associate Director
OPP Registration Division
US Environmental Protection Agency

Begin forwarded message:

From: "Aubee, Catherine" <Aubee.Catherine@epa.gov>
Date: July 30, 2020 at 1:44:21 PM EDT
To: "Motilall, Christina" <Motilall.Christina@epa.gov>
Cc: "Siedschlag, Gregory" <Siedschlag.Gregory@epa.gov>
Subject: Re: Service Dog Killed by Seresto

Hi Christina,

If you would like to set up a meeting next week with myself and the following folks, we can discuss:

Erik Kraft
Jackie Herrick
Jamey Shuler

Best,
Catherine
Associate Director
OPP Registration Division
US Environmental Protection Agency

On Jul 30, 2020, at 1:38 PM, Motilall, Christina <Motilall.Christina@epa.gov> wrote:

Hi all,

We are going to discuss this in house with FEAD but I wanted to ask, what is our process for responding to citizen complaints such as this?

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Any information is appreciated! Thank you!

From: Aubee, Catherine <Aubee.Catherine@epa.gov>
Sent: Thursday, July 30, 2020 9:59 AM
To: Miller, Robert <Miller.Robert@epa.gov>
Cc: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; McFarley, Heather <McFarley.Heather@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Shuler, Jamey <Shuler.Jamey@epa.gov>; Mastrotta, Nicholas <Mastrotta.Nicholas@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Odenkirchen, Edward <Odenkirchen.Edward@epa.gov>; Smith, Kimberly <Smith.Kimberly@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>; Kraft, Erik <Kraft.Erik@epa.gov>
Subject: RE: Service Dog Killed by Seresto

Hello Bob,

Thank you for your continued efforts in collecting and transmitting this information. I appreciate that you included the RD team members on this one – I am also looping in the currently acting branch chief, Erik Kraft.

Best,
Catherine

From: Miller, Robert <Miller.Robert@epa.gov>
Sent: Thursday, July 30, 2020 9:54 AM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; McFarley, Heather <McFarley.Heather@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Shuler, Jamey <Shuler.Jamey@epa.gov>; Mastrotta, Nicholas <Mastrotta.Nicholas@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Odenkirchen, Edward <Odenkirchen.Edward@epa.gov>; Smith, Kimberly <Smith.Kimberly@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Subject: Service Dog Killed by Seresto

Good morning Catherine:

Attached is an update to a Seresto collar incident that caused a service dog their life. A

Ex. 5 Deliberative Process (DP)

We've received over 73,000 incident reports for Seresto. 1,650 of these reports were pet deaths.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Take care,

Bob

Robert A. Miller
6(a)(2) Coordinator
Information Technology and Resource Management Division
EPA Office of Pesticide Programs
Mail Code 7508P
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W., Washington D.C.

(703) 347-8012
miller.robert@epa.gov

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 7/30/2020 2:12:09 PM
To: Kraft, Erik [Kraft.Erik@epa.gov]; Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]
CC: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: FW: Discuss Seresto Incident Profile
Attachments: Discuss Seresto Incident Profile.ics

Internal, deliberative

Erik,

Attaching some background info on the Seresto issue. We start to see a few of these incident reports each season.

Before I went on detail, Jamey, Jackie, and Letu (in summers) were researching this issue and starting to put together some options for management based on discussions with OGC. Two main recommendations: **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

take a look and provide some feedback, along with Jackie, who had previously reviewed.

There are additional slides in the attached calendar invitation which should provide useful information – you may want to update them. Please take appropriate precautions with any CBI.

Please familiarize yourself with this issue and then let's discuss how you'd like to proceed. (I will ask Anita to set up a general – I see you don't have one on the calendar yet.) As things move forward, we should continue to coordinate with PRD, as well.

Best,
Catherine

From: Aubee, Catherine
Sent: Thursday, February 06, 2020 10:38 AM
To: Shuler, Jamey <Shuler.Jamey@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: FW: Discuss Seresto Incident Profile

FYI for current discussions

Message

From: Barber, Delores [barber.delores@epa.gov]
Sent: 8/3/2020 5:59:34 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
CC: Aubee, Catherine [Aubee.Catherine@epa.gov]
Subject: RE: Service Dog Killed by Seresto

Okay. Thanks, Marietta.

From: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Sent: Monday, August 3, 2020 1:53 PM
To: Barber, Delores <barber.delores@epa.gov>
Cc: Aubee, Catherine <Aubee.Catherine@epa.gov>
Subject: FW: Service Dog Killed by Seresto

Delores, We'd like to discuss at our next ITRMD/RD general. Thank you!

From: Aubee, Catherine <Aubee.Catherine@epa.gov>
Sent: Thursday, July 30, 2020 10:00 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: FW: Service Dog Killed by Seresto

For awareness -

Best,
Catherine

From: Aubee, Catherine
Sent: Thursday, July 30, 2020 9:59 AM
To: Miller, Robert <Miller.Robert@epa.gov>
Cc: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; McFarley, Heather <mcfarley.heather@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Shuler, Jamey <Shuler.Jamey@epa.gov>; Mastrotta, Nicholas <Mastrotta.Nicholas@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Odenkirchen, Edward <Odenkirchen.Edward@epa.gov>; Smith, Kimberly <Smith.Kimberly@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>; Kraft, Erik <Kraft.Erik@epa.gov>
Subject: RE: Service Dog Killed by Seresto

Hello Bob,

Thank you for your continued efforts in collecting and transmitting this information. I appreciate that you included the RD team members on this one – I am also looping in the currently acting branch chief, Erik Kraft.

Best,
Catherine

From: Miller, Robert <Miller.Robert@epa.gov>
Sent: Thursday, July 30, 2020 9:54 AM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; McFarley, Heather <McFarley.Heather@epa.gov>; Miller, David

<Miller.DavidJ@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Shuler, Jamey <Shuler.Jamey@epa.gov>; Mastrota, Nicholas <Mastrota.Nicholas@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Odenkirchen, Edward <Odenkirchen.Edward@epa.gov>; Smith, Kimberly <Smith.Kimberly@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>

Subject: Service Dog Killed by Seresto

Good morning Catherine:

Attached is an update to a Seresto collar incident that caused a service dog their life.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

We've received over 73,000 incident reports for Seresto. 1,650 of these reports were pet deaths.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Take care,

Bob

Robert A. Miller
6(a)(2) Coordinator
Information Technology and Resource Management Division
EPA Office of Pesticide Programs
Mail Code 7508P
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W., Washington D.C.

(703) 347-8012
miller.robert@epa.gov

Message

From: Kraft, Erik [Kraft.Erik@epa.gov]
Sent: 9/30/2020 3:03:28 PM
To: Aubee, Catherine [Aubee.Catherine@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: RE: my general agenda

I will reach out again to her.

From: Aubee, Catherine <Aubee.Catherine@epa.gov>
Sent: Wednesday, September 30, 2020 11:02 AM
To: Kraft, Erik <Kraft.Erik@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: RE: my general agenda

Hi Erik,

I have a calendar conflict for your general on Thursday. Could you please provide an update on Anna-Katrina Briley's status?

Ex. 6 Personal Privacy (PP)

Ex. 6 Personal Privacy (PP)

Best,
Catherine

From: Kraft, Erik <Kraft.Erik@epa.gov>
Sent: Monday, September 28, 2020 3:24 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Coleman, Anita <Coleman.Anita@epa.gov>
Subject: my general agenda

Hi Marietta,

I'd like to discuss:

1. Broflanilide status update
2. Seresto update
3. HR issues- hiring, Bobby & Letu

Thanks
Erik

Message

From: Kraft, Erik [Kraft.Erik@epa.gov]
Sent: 9/14/2020 4:43:51 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]
CC: Aubee, Catherine [Aubee.Catherine@epa.gov]; Coleman, Anita [Coleman.Anita@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: Agenda items to discuss at my General

Hi Marietta,

Items I'd like to discuss at my general this Thursday.

1. Broflanalide **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

2. Cyclaniliprole- **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

3. Seresto collar- any further guidance from the RD IO?

4. HR Issues- **Ex. 6 Personal Privacy (PP)**

Ex. 6 Personal Privacy (PP)

Thanks,
Erik

Message

From: Barber, Delores [barber.delores@epa.gov]
Sent: 8/24/2020 6:42:19 PM
To: Syed, Hamaad [Syed.Hamaad@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: RE: General RD & ITRMD - 8/24/2020

Thanks, Hamaad.





From: Syed, Hamaad <Syed.Hamaad@epa.gov>
Sent: Monday, August 24, 2020 2:37 PM
To: Barber, Delores <barber.delores@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Syed, Hamaad <Syed.Hamaad@epa.gov>
Subject: General RD & ITRMD - 8/24/2020

General RD & ITRMD - 8/24/2020

Monday, August 24, 2020
1:36 PM

Meeting Date: 8/24/2020 1:30 PM
Location: Microsoft Teams Meeting
Link to Outlook Item: [click here](#)
Invitation Message

Participants

-  [Barber, Delores](#) (Meeting Organizer)
-  [Echeverria, Marietta](#)
-  [Aubee, Catherine](#) (Accepted in Outlook)
-  [Rosenblatt, Daniel](#)
-  [Syed, Hamaad](#) (Accepted in Outlook)

Notes

1. Marietta spoke about front end delays
Marietta suggested that Aswathy should come brief Delores, Kim, Raderrio, Mick, and Steve S about the issue and possible remedies.

2. Dan discussed the Registration Draft Audit Report

•

Ex. 5 Deliberative Process (DP)

3. Seresto dog collar emails. Better internal communication around this discussion. Delores will address it.

4. Delores explained the OCSPP Awards nomination process
<<Award Forms.msg>>

Created with Microsoft OneNote 2016.

Message

From: Wilbur, Donald [Wilbur.Donald@epa.gov]
Sent: 10/21/2020 12:12:06 PM
To: Vogel, Dana [Vogel.Dana@epa.gov]; Akerman, Gregory [Akerman.Gregory@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
CC: Coleman, Anita [Coleman.Anita@epa.gov]
Subject: RE: HED-RD Bi-weekly General

Here are the topics we have:

- I-glufosinate
- Seresto workgroup to call in data
- Aldicarb
- FR issues for OGC
- Dicamba

Donald Wilbur

Deputy Director
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW, MC 7509P, Washington DC 20460
☎ (703) 347-8894 | ✉ wilbur.donald@epa.gov

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-----Original Appointment-----

From: Vogel, Dana <Vogel.Dana@epa.gov>
Sent: Thursday, August 27, 2020 10:39 AM
To: Vogel, Dana; Wilbur, Donald; Akerman, Gregory; Echeverria, Marietta; Aubee, Catherine
Cc: Coleman, Anita
Subject: HED-RD Bi-weekly General
When: Wednesday, October 21, 2020 2:00 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Join Microsoft Teams Meeting

Ex. 6 PP - conference code/call in number

United States, Washington DC (Toll)

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ED_005739D_00000790-00001

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Message

From: Kraft, Erik [Kraft.Erik@epa.gov]
Sent: 10/28/2020 11:53:05 AM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]
CC: Coleman, Anita [Coleman.Anita@epa.gov]
Subject: agenda for my general this week

Hi Marietta,

I'd like to discuss

1. Broflanilide- status of where we are what needs to happen to post by Friday
2. Spartan (any new updates you've got from management, we got a few more comments from Mike that we will work on after Broflanilide posts
3. Seresto update
4. PARS reviews update- **Ex. 6 Personal Privacy (PP)**

Thanks

Erik

Message

From: Vogel, Dana [Vogel.Dana@epa.gov]
Sent: 9/9/2020 2:44:28 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]; Akerman, Gregory [Akerman.Gregory@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
CC: Coleman, Anita [Coleman.Anita@epa.gov]
Subject: RE: HED-RD Bi-weekly General

Thanks!! I will cancel it.

From: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Sent: Wednesday, September 09, 2020 10:39 AM
To: Wilbur, Donald <Wilbur.Donald@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Cc: Coleman, Anita <Coleman.Anita@epa.gov>
Subject: RE: HED-RD Bi-weekly General

Here are the brief updates. I think we can cancel unless you need more info:

- Glufosinate – we still need to circle back to Rachel
- Broflo – **Ex. 5 Deliberative Process (DP)**
- Formetante – resolved – Mike got back to Gowan with our response. No additional info needed.
- Seresto – we talked to Elissa and agreed that we should offer to brief Ed on the issue. We are going to get his feedback during our next general.

From: Wilbur, Donald <Wilbur.Donald@epa.gov>
Sent: Wednesday, September 9, 2020 9:42 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Cc: Coleman, Anita <Coleman.Anita@epa.gov>
Subject: RE: HED-RD Bi-weekly General

The follow-up items I have listed are:

- I-glufosinate – OGC follow up
- Broflanilide – **Ex. 5 Deliberative Process (DP)**
- Formetanate – TOR status
- Seresto workgroup data call-in

Donald Wilbur
Deputy Director
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW, MC 7509P, Washington DC 20460
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From: Vogel, Dana <Vogel.Dana@epa.gov>
Sent: Wednesday, September 9, 2020 9:02 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Coleman, Anita <Coleman.Anita@epa.gov>
Subject: RE: HED-RD Bi-weekly General

Just follow up the items from last general. If you have any updates we can meet but if not we can cancel!

From: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Sent: Wednesday, September 09, 2020 8:51 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Coleman, Anita <Coleman.Anita@epa.gov>
Subject: RE: HED-RD Bi-weekly General

Not that I can think of. You guys?

From: Vogel, Dana <Vogel.Dana@epa.gov>
Sent: Wednesday, September 9, 2020 5:51 AM
To: Wilbur, Donald <Wilbur.Donald@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Coleman, Anita <Coleman.Anita@epa.gov>
Subject: RE: HED-RD Bi-weekly General

Good morning, any items for the general?

-----Original Appointment-----

From: Arceo, Julian **On Behalf Of** Vogel, Dana
Sent: Thursday, August 27, 2020 10:39 AM
To: Vogel, Dana; Wilbur, Donald; Akerman, Gregory; Marietta Echeverria; Aubee, Catherine
Cc: Coleman, Anita
Subject: HED-RD Bi-weekly General
When: Wednesday, September 09, 2020 2:00 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Join Microsoft Teams Meeting

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United States, Washington DC (Toll)

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Message

From: Coleman, Anita [Coleman.Anita@epa.gov]
Sent: 11/10/2020 7:22:12 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: RE: Seresto

Thanks.

From: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Sent: Tuesday, November 10, 2020 1:52 PM
To: Coleman, Anita <Coleman.Anita@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: RE: Seresto

RD-IO review

It's an internal presentation for a briefing that Erik is preparing for. thanks

From: Coleman, Anita <Coleman.Anita@epa.gov>
Sent: Tuesday, November 10, 2020 1:22 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: FW: Seresto

Hello,

Help please. I am not sure where to place this presentation. Is this proposed Seresto draft presentation a part of the All Hands meeting, speaking engagement???

Thanks.

Anita

From: Kraft, Erik <Kraft.Erik@epa.gov>
Sent: Tuesday, November 10, 2020 10:41 AM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Cc: Coleman, Anita <Coleman.Anita@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: Seresto

Hi RD IO,

Attached is the draft Seresto presentation. We are still waiting on a few final edits from PRD, but I wanted to send to you the draft as it currently stands, as my detail ends this week. It outlines the issues, history, and suggested paths forward.

Thanks
Erik

Message






From: Syed, Hamaad [Syed.Hamaad@epa.gov]
Sent: 8/24/2020 6:37:11 PM
To: Barber, Delores [barber.delores@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Syed, Hamaad [Syed.Hamaad@epa.gov]
Subject: General RD & ITRMD - 8/24/2020
Attachments: Award Forms

General RD & ITRMD - 8/24/2020

Monday, August 24, 2020
1:36 PM

Meeting Date: 8/24/2020 1:30 PM
Location: Microsoft Teams Meeting
Link to Outlook Item: [click here](#)
Invitation Message

Participants

-  Barber, Delores (Meeting Organizer)
-  Echeverria, Marietta
-  Aubee, Catherine (Accepted in Outlook)
-  Rosenblatt, Daniel
-  Syed, Hamaad (Accepted in Outlook)

Notes

1. Marietta spoke about front end delays
Marietta suggested that Aswathy should come brief Delores, Kim, Raderrio, Mick, and Steve S about the issue and possible remedies.
2. Dan discussed the Registration Draft Audit Report

-
- **Ex. 5 Deliberative Process (DP)**

3. Seresto dog collar emails. Better internal communication around this discussion. Delores will address it.
4. Delores explained the OCSP Awards nomination process
<<Award Forms.msg>>

Created with Microsoft OneNote 2016.

Message

From: Vogel, Dana [Vogel.Dana@epa.gov]
Sent: 12/16/2020 1:31:04 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]; Akerman, Gregory [Akerman.Gregory@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
CC: Coleman, Anita [Coleman.Anita@epa.gov]
Subject: RE: HED-RD Bi-weekly General

Ok Thanks!! Here is our list:

- Harmonization document - Nancy comments - ready for OGC?
- Tebuconazole - PRIA and DRA with different tox and EDWCs
- Aldicarb - citrus - CRA
- Dicamba incident report
- China/ICAMA coordination on import MRLs – RD
- Seresto data call in – update
- L-glufosinate – multiple submissions – OGC input?
- Joint Review followup

From: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Sent: Wednesday, December 16, 2020 8:29 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Cc: Coleman, Anita <Coleman.Anita@epa.gov>
Subject: RE: HED-RD Bi-weekly General

I'm checking with BCs and will let you know,

From: Vogel, Dana <Vogel.Dana@epa.gov>
Sent: Wednesday, December 16, 2020 7:30 AM
To: Wilbur, Donald <Wilbur.Donald@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Cc: Coleman, Anita <Coleman.Anita@epa.gov>
Subject: HED-RD Bi-weekly General

Hi All, Any items for the general?

Director, Health Effects Division
Office of Pesticide Programs
703-305-0874

Message

From: Saunders, Jennifer [Saunders.Jennifer@epa.gov]
Sent: 1/27/2021 3:15:48 PM
To: Aubee, Catherine [Aubee.Catherine@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: FW: Seresto - Midwest Center for Investigative Reporting
Importance: High

FYI, Jackie is starting to work on it.

From: Overbey, Dian <Overbey.Dian@epa.gov>
Sent: Wednesday, January 27, 2021 10:00 AM
To: Saunders, Jennifer <Saunders.Jennifer@epa.gov>
Subject: FW: Seresto - Midwest Center for Investigative Reporting
Importance: High

Hi Jenn,

I received this press inquiry yesterday afternoon, and it looks like it may be a bear to answer. I'm trying to get incident information from ISB on EPA Reg. No. 11556-155, which is the Seresto collar. Also trying to see exactly what his FOIA request comprised.

Is Julie Breeden-Alemi still in your branch? Is she the best person to work with on the responses to this?

Hope you and your family are all doing well!

Dian

From: Labbe, Ken <Labbe.Ken@epa.gov>
Sent: Tuesday, January 26, 2021 4:09 PM
To: Dennis, Allison <Dennis.Allison@epa.gov>; OPS CSID CB <OPS_CSID_CB@epa.gov>
Subject: FW: Seresto - Midwest Center for Investigative Reporting

Hi all, Please see inquiry below. Deadline EOD Friday.

Thanks,

Ken

From: Johnathan Hettinger <jhettinger@investigatemidwest.org>
Sent: Tuesday, January 26, 2021 4:05 PM
To: Press <Press@epa.gov>; Daguiard, Robert <Daguiard.Robert@epa.gov>; Labbe, Ken <Labbe.Ken@epa.gov>; Jones, Enesta <Jones.Enesta@epa.gov>
Subject: Seresto - Midwest Center for Investigative Reporting

Hello,

I'm a reporter with the Midwest Center for Investigative Reporting, a nonprofit newsroom based in Champaign, Illinois, that covers agribusiness. I am working on a story about EPA incident data surrounding Seresto collars. It is my understanding that there have been a significant amount of incidents surrounding the pesticides in the collars, and I had some questions.

According to a records request of EPA documents, there have been at least 75,000 incident reports involving pets, including 1,698 deaths. Is this a high number? Why is it still sold? Is there any sort of threshold for removing the collar from the market?

It is my understanding that these incidents do not include the main incident reporting system, which likely has additional incidents. Do you have more information about the number of incidents?

California toxicologists said the Bayer studies the EPA relied on to approve the collars underestimated the harm to adult dogs and cats. However, the EPA approved them. What science is there to support these registrations? How can customers know that these are safe to use?

There have been at least 907 human-related incidents since 2013, according to EPA data. Is this a high number? Is there any sort of threshold for removing the collar from the market?

It is my understanding that Bayer knew about these incidents for years, prior to selling dog collars to Elanco. Did Bayer make Elanco aware of these issues when selling the product to Elanco?

From my understanding talking with former EPA staff, Health Canada denied to approve Seresto because of the incident data. Do you have any response to this?

If possible, I would very much like to speak to someone for this story. Please let me know if you would have some time. My deadline is Friday, end-of-day.

Thanks,
Johnathan Hettinger
Investigative Reporter
Midwest Center for Investigative Reporting
217-493-9791

Message

From: Saunders, Jennifer [Saunders.Jennifer@epa.gov]
Sent: 2/8/2021 10:36:49 PM
To: Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: General agenda for tomorrow morning

Hi IO, please see my general agenda below, it's light (haha although it doesn't look like it), thanks!

Quick Updates/Questions

- 1) **PERC charter:** Thanks for the comments, they were great and resulted in pretty big improvements. Revised charter is with you for signature.
- 2) **Spot on priorities:** Are we equally prioritizing the conversions and the extensions? Are these prioritized over nonPRIAs? Jackie trained the newer staff on spot ons last week so we're ready to start moving.
- 3) **Seresto:** We're having a meeting on the 24th across the divisions to go through the PowerPoint to get everyone on the same page in advance of presenting to you.
- 4) **PETA:** We had another productive meeting with them, looks like we'll be having a few webinars in the fall, one at which EPA will present, followed by the workshop in the summer. We have a tentative list of webinar topics and some high level info on the workshop, including potential steering committee members and workshop participants.
- 5) **Staff development/mentoring update**
- 6) **RAB8 guideline progress:** Short version, they're still wonderful.
- 7) **Hiring:** RMs, GS 14
- 8) What exactly is the **adaptive management meeting** and what's expected of me? I'm going to meet with one of the BCs but if there's time I'd like to get your perspectives.

Jennifer Urbanski Saunders, Ph.D., Chief
Invertebrate & Vertebrate Branch I
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0156

Message

From: Overbey, Dian [Overbey.Dian@epa.gov]
Sent: 3/2/2021 7:49:34 PM
To: Saunders, Jennifer [Saunders.Jennifer@epa.gov]; Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: URGENT: Needed ASAP Seresto Flea Collar Followup
Importance: High

The story resulting from the press inquiry on Seresto collars that we responded to a couple of weeks ago published in USA Today, and we have a follow-up inquiry from the NY Post. Shamus would like to get this to the OPP IO ASAP (3:00), so I'd appreciate your taking a quick look at this right away.

According to the report, the EPA has received thousands of complaints from pet owners about these collars, but has not warned the public about a potential problem involving the products.

Is it accurate that the EPA has received reports of 1,698 pet deaths attributed to the collars and more than 75,000 incident reports about the products and nearly 1,000 incidents of human harm?

Response:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Dian D. Overbey
Communications Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Potomac Yard S-8927
(703) 305-5018 (O)
(571) 302-0764 (OC)

Ex. 6 Personal Privacy (PP)

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 3/2/2021 8:16:38 PM
To: Saunders, Jennifer [Saunders.Jennifer@epa.gov]; Overbey, Dian [Overbey.Dian@epa.gov]; Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]
Subject: RE: URGENT: Needed ASAP Seresto Flea Collar Followup

Hello all:

I have been in meetings and have not had an opportunity to review and provide suggested edits. I think it is important

Ex. 5 Deliberative Process (DP)

Best,
Catherine

From: Saunders, Jennifer <Saunders.Jennifer@epa.gov>
Sent: Tuesday, March 02, 2021 3:09 PM
To: Overbey, Dian <Overbey.Dian@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: URGENT: Needed ASAP Seresto Flea Collar Followup

Dian, I think you had a previous answer related to all the data that EPA requires for initial registration of a product?

From: Overbey, Dian <Overbey.Dian@epa.gov>
Sent: Tuesday, March 02, 2021 3:05 PM
To: Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: URGENT: Needed ASAP Seresto Flea Collar Followup

Those numbers are accurate. The reporter who wrote the USA Today piece got them from a document request and we confirmed them.

Ex. 5 Deliberative Process (DP)

Also, reporter has two more questions I'm working on.

Knowing the risks why did the EPA allow this product from going to market?
Why didn't the EPA act sooner?

From: Saunders, Jennifer <Saunders.Jennifer@epa.gov>
Sent: Tuesday, March 02, 2021 3:03 PM
To: Overbey, Dian <Overbey.Dian@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: URGENT: Needed ASAP Seresto Flea Collar Followup

Hi Dian, I don't know whether those incident numbers are accurate, I'm copying Cathryn Britton in case she knows.

I don't think

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Overbey, Dian <Overbey.Dian@epa.gov>

Sent: Tuesday, March 02, 2021 3:00 PM

To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>

Subject: RE: URGENT: Needed ASAP Seresto Flea Collar Followup

Please do the best you can. That's all we can ask.

Yes, I think

Ex. 5 Deliberative Process (DP)

Dian

From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Sent: Tuesday, March 02, 2021 2:57 PM

To: Overbey, Dian <Overbey.Dian@epa.gov>; Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>

Subject: RE: URGENT: Needed ASAP Seresto Flea Collar Followup

Hi Dian,

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) ?

Thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Overbey, Dian <Overbey.Dian@epa.gov>

Sent: Tuesday, March 02, 2021 2:50 PM

To: Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>

Subject: URGENT: Needed ASAP Seresto Flea Collar Followup

Importance: High

The story resulting from the press inquiry on Seresto collars that we responded to a couple of weeks ago published in USA Today, and we have a follow-up inquiry from the NY Post. Shamus would like to get this to the OPP IO ASAP (3:00), so I'd appreciate your taking a quick look at this right away.

According to the report, the EPA has received thousands of complaints from pet owners about these collars, but has not warned the public about a potential problem involving the products.

Is it accurate that the EPA has received reports of 1,698 pet deaths attributed to the collars and more than 75,000 incident reports about the products and nearly 1,000 incidents of human harm?

Response:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Dian D. Overbey

Communications Branch

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

Potomac Yard S-8927

(703) 305-5018 (O)

(571) 302-0764 (OC)

Ex. 6 Personal Privacy (PP)

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 3/2/2021 9:26:17 PM
To: Vogel, Dana [Vogel.Dana@epa.gov]; Cyran, Carissa [Cyran.Carissa@epa.gov]; Overbey, Dian [Overbey.Dian@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]; Akerman, Gregory [Akerman.Gregory@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]
CC: Ozmen, Shamus [Ozmen.Shamus@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Olinger, Christine [Olinger.Christine@epa.gov]; VanAlstine, Julie [VanAlstine.Julie@epa.gov]
Subject: RE: Redraft of redraft of NY Post press inquiry

<!--[if lte mso 15 || CheckWebRef]-->

Aubee, Catherine has shared a OneDrive for Business file with you. To view it, click the link below.

 DRAFT Seresto press response 2021-03-02.docx

<!--[endif]-->

Attaching a shared file where I will be making suggested edits; others are welcome. I'll send a note once complete.

Best,
Catherine

From: Vogel, Dana <Vogel.Dana@epa.gov>
Sent: Tuesday, March 02, 2021 4:24 PM
To: Cyran, Carissa <Cyran.Carissa@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>
Cc: Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Olinger, Christine <Olinger.Christine@epa.gov>; VanAlstine, Julie <VanAlstine.Julie@epa.gov>
Subject: RE: Redraft of redraft of NY Post press inquiry

Thanks Carissa, David M has some suggested edits and will send them asap. No other comments (other than david's) from HED.

Dv

From: Cyran, Carissa <Cyran.Carissa@epa.gov>
Sent: Tuesday, March 02, 2021 4:18 PM
To: Overbey, Dian <Overbey.Dian@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>
Cc: Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Olinger, Christine <Olinger.Christine@epa.gov>; VanAlstine, Julie <VanAlstine.Julie@epa.gov>
Subject: Re: Redraft of redraft of NY Post press inquiry

+ HED

From: Overbey, Dian <Overbey.Dian@epa.gov>

Sent: Tuesday, March 2, 2021 4:12 PM

To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>

Cc: Cyran, Carissa <Cyran.Carissa@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>

Subject: Redraft of redraft of NY Post press inquiry

Those numbers are an accurate representation of the number of incidents reported to EPA over a period of eight years.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Dian D. Overbey

Communications Branch

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

Potomac Yard S-8927

(703) 305-5018 (O)

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Ex. 6 Personal Privacy (PP)